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Bio-Identical Hormone Therapy: Understanding Women's Decision-Making Process and Family Physicians' Views

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Graduate Program in Family Medicine
A thesis submitted in partial fulfillment of the requirements for the degree in Master of Clinical Science
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**BIO-IDENTICAL HORMONE THERAPY: UNDERSTANDING WOMEN'S
DECISION-MAKING PROCESS AND FAMILY PHYSICIANS' VIEWS**

(Thesis format: Integrated Article)

by

Lemmese AlWatban MBBS(Honours),CCFP

Graduate Program In Family Medicine

A thesis submitted in partial fulfillment of the requirements for the degree of
Master of Clinical Science in Family Medicine (MClSc)

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Abstract

This thesis explored women's and family physicians' experiences with Bio-identical Hormone Therapy (BHT). It aimed to develop a deeper understanding of women's decision-making process in choosing this therapeutic modality, and the influence family physicians may have on this process. To capture the phenomenon under study, two complementary and sequential qualitative studies were conducted. The studies involved in-depth interviews with women using BHT and family physicians that care for this population. The collective findings of both studies demonstrated the complexity of menopause care. The findings illuminated the major factors involved in women's BHT decision-making process. It also offered important information about the role of the family physician and the patient-physician relationship in the journey of women choosing to use BHT; in particular, the value placed on family physicians spending adequate time exploring women's experiences, listening to their concerns and being open to the independence of their therapeutic choices.

Key Words: Menopause, BHT, Bio-identical Hormones, Decision-making, Family medicine, Patient-Physician Relationship.

Dedication

This thesis is dedicated to the memory of my grandfather, William Leask

A wise man who could always see the funny side of life

Co-Authorship Statement

The research for this thesis was conceived, planned, conducted and reported by the author.

The following contributions were made:

Dr Graham Reid, Dr Amanda Terry and Dr John Jordan provided guidance and advice throughout the planning, execution, analysis, and reporting of the qualitative studies in this thesis

Dr Graham Reid and Dr Amanda Terry also contributed to the thematic analysis of the qualitative studies from both sets of in-depth interviews.

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“If there is no struggle, there is no progress.”

~Frederick Douglass

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Chapter 1

Introduction

Some women have chosen to use Bio-identical Hormone Therapy (BHT) to manage menopause, despite considerable controversy concerning the safety and efficacy of this therapeutic modality.¹⁻⁴ This thesis aimed to gain a deeper understanding of this phenomenon through exploring the decision-making process of women who chose to use BHT to manage menopause, and the influence of family physicians on this process.

1.1 The Purpose of the Introductory Chapter

This chapter will review the history and significance of hormone therapy in menopause, introduce the Bio-identical Hormone Therapy (BHT) approach, and outline the differences between BHT and conventional hormone therapy. To provide a foundation for the qualitative studies in the subsequent chapters, the definitions, prevalence and a literature review of both women's and physicians' experiences with BHT are highlighted. Finally, an overview of the research design used in the qualitative studies is presented.

1.2 The Significance of Managing Menopause

The issue of menopausal health is of significance to society in general because of its universality - it affects all women. Menopause and the peri-menopausal period are important transitional chapters in the lives of most women. Natural menopause as defined by the World Health Organization (WHO) is 12 months of amenorrhea after the last period.⁵ This is usually determined in retrospect when a woman reports no menses for

one year. The average age of menopause is approximately 51 years, with a range of 40 to 55 years.⁶ The majority of women in advanced societies can expect to live 30 years beyond this point.⁶ The female population in Canada is aging; in 2010 the 45 to 64 year old age group made up about 28% of females, and is expected to increase over time.⁷

Although menopause is a natural process, it may be a time where varying degrees of psychological and physical symptoms are experienced. Hot flashing, and its accompanying symptoms including sweating, palpitations, apprehension, and anxiety, affect 60-80% of women entering menopause.⁸ Although most menopausal women (60%) experience hot flashes for less than 7 years, up to 15% report that hot flashes persist for 15 years or more.⁹ Vasomotor symptoms (i.e., hot flashes and night sweats) contribute to the woman's discomfort, and can have considerable adverse effects on her quality of life (QOL), which can result in a requirement for medical management.¹⁰ Multiple therapeutic options are available to help manage menopause including: lifestyle modification, diet, exercise, herbal therapies, antidepressants and hormonal therapy; these have varying success.⁸ Hormone therapy has been shown to be a superior therapeutic agent in relieving vasomotor symptoms and their potential consequences (e.g., diminished sleep quality, irritability, and reduced QOL).¹¹⁻¹⁴

1.3 History of Hormone Therapy in Menopause

Hormone Therapy (HT) also known as Hormone Replacement Therapy (HRT) is a medication that utilizes hormones, usually estrogen and progestin (a synthetic form of progesterone), in the management of menopause.¹⁵ The estrogen (estradiol, estradiol 17 β , or conjugated equine estrogen) can be oral or transdermal and the progestin can be oral, transdermal, or delivered via an intrauterine device.⁸

In the 1990s and up until early 2002, women were routinely prescribed HRT as short-term therapy to help relieve symptoms associated with menopause, as well as a long-term therapy for prevention of coronary heart disease (CHD) and osteoporosis.^{16, 17} It was estimated in the 1990s that more than one third of postmenopausal women aged 50 to 74 years were taking HRT.¹⁸

Clinical practice patterns changed dramatically after the publication of the Women's Health Initiative (WHI) in 2002, a landmark randomised control trial of HRT that aimed to see if the rate of CHD and other events was lower in women who used HRT compared to placebo.¹⁹ The WHI study showed an increase in the risks of venous thromboembolism, cardiovascular disease, stroke and breast cancer with combined estrogen/progestin therapy.^{19, 20} Overall HRT prescriptions decreased by around 38 percent in the first year after the WHI was published.^{21, 22} The findings of the WHI were also widely publicized in the popular press, producing immediate and major impacts on women's use of HRT.^{21, 23} It has been estimated that up to 70% of women taking HRT stopped within the first year of publication, and 26% reported losing trust in medical recommendations in general.^{24, 25}

More recent publications have criticized the wide public release of the WHI findings, and have questioned the interpretation and generalizability of its findings.²⁶⁻²⁸ Many newer studies, as well as secondary analyses of the WHI, propose a re-evaluation of the WHI's initial findings.^{26, 29, 30} The age of women when they present for menopause care, the timing of initiating HRT, as well as type and route of hormones have been proposed as contributing factors to cardiovascular and breast cancer risk.^{26, 29-32} As a result, hormone therapy prescribing practices have shifted again. Currently there is an emphasis

on lifestyle choices for health promotion and disease prevention; reserving hormonal therapy for symptomatic women.⁸

Even though at present multiple menopause societies, including The Society of Obstetricians and Gynaecologists of Canada (SOGC) and the North American Menopause Society (NAMS), have supported the use of HRT for the management of symptomatic menopausal women,^{8, 33} there still remains much uncertainty among women and their health care providers about the safety of HRT.^{31, 34} As a result, some women have chosen to use “bio-identical hormonal therapy (BHT)” or “natural hormones” as an alternative to conventional hormone preparations in the belief that they are safer.^{4, 35, 36}

1.4 Terms and Definitions

One area of confusion in clinical practice is with the use of the term “bio-identical”. It has been used to refer to many commercially available pharmaceutical hormone therapy products containing hormones that are chemically identical to the hormones produced naturally by women such as 17 β -estradiol or progesterone.¹³ However, the term is also most often used to describe custom-made hormone formulations (called Bio-identical hormone therapy, or BHT) that are compounded for an individual according to a healthcare provider’s prescription.¹³ The hormones most commonly compounded are estradiol, estrone, estriol and progesterone.¹⁻³ In this thesis the term BHT will refer to the latter definition. Thus, conventional hormone therapy or HRT will refer to all commercially available hormone products, regardless of how well their hormone composition resembles naturally occurring hormones, and will include all routes of hormone use.

1.5 Differences between BHT and HRT

In addition to the difference in how BHT is made compared to HRT (i.e. pharmacy compounded vs. commercially manufactured), there is a difference in the philosophy of care and the rationale for prescribing specific hormones.^{3, 37-39} A good example is the role of progestogens (i.e. natural progesterone and synthetic progestin) in hormone therapy. Currently the primary menopause-related indication for progestogen or progestin use in HRT is to counteract the increased risk of endometrial cancer from systemic estrogen use.⁸ The North American Menopause Society recommends that all women with an intact uterus who use systemic estrogen should also be prescribed adequate progestogen, while women without a uterus should not be prescribed a progestogen.¹³

On the other hand, BHT prescribers believe progestogen, and specifically progesterone, has a major role in relieving menopausal symptoms.^{3, 37-40} The theory of “estrogen dominance” as a result of the more rapid decline of progesterone compared to estrogen⁴¹ is thought by BHT providers to contribute to menopausal symptoms.⁴⁰ Thus, BHT practice would involve prescribing hormone components (estrogen and progesterone) based on the assessment of the women’s presenting symptoms and a measurement of salivary or blood hormone levels.^{38, 39}

There is, however, very little published information about the use of BHT, their safety or their efficacy. The International Menopause Society (IMS) and NAMS do not endorse their use.^{33, 42} NAMS also warns against possible increased risks to the women using these products since: they have not been tested for efficacy or safety; safety information is not consistently provided to women along with their prescription, as is required with commercially available HT; and batch standardization and purity may be uncertain.³³

Expense is also an issue, as many custom compounded preparations are not covered by medical insurance, resulting in higher costs to the patient.³³ In addition, there appears to be concern that the terms “bio-identical” and “natural” may be misleading to women, suggesting that they are safer than HRT and influencing women’s decisions to use them.^{4,} 36, 43, 44

1.6 Prevalence of BHT Use

Data on the extent of BHT use in the population are scarce; one study estimates the prevalence of compounded BHT use to be about 20% among menopausal women seeking care at an academic women’s health centre in the USA.³⁵ Alternatively, the prevalence of complementary and alternative medicine (CAM) use among menopausal and perimenopausal women ranges from 50%-75% in North America and the UK,⁴⁵⁻⁴⁸ and one estimate suggests 95% of women would try alternative therapies before considering HRT.⁴⁹ Since CAM is an overarching term that includes many different therapeutic modalities and most studies did not specifically exclude BHT from their reports on CAM prevalence, the extent of BHT use may be higher than predicted.

1.7 Literature Review

There are numerous publications regarding BHT; however, the majority are review articles and physicians’ opinions about the overall BHT approach. Topics include: differences and similarities to HRT; discussions on safety and efficacy; and concerns about unsupported therapeutic claims.^{1, 2, 4, 44, 50-53} There is a scarcity of original studies that examine the BHT approach. A few studies were identified that directly explored patients’ and health care providers’ experiences and views of BHT, these are described below.

1.7.1 Women's Perspective on BHT

Only four studies reported on women's BHT experiences. Of these, two described positive experiences - the restoration of health and alleviation of menopausal symptoms for women taking BHT.^{35, 54} One qualitative study focused on women's ability to access BHT and the factors which either impeded or facilitated that access.⁵⁵ Another cross sectional study looked into women's beliefs and understanding about the term "bio-identical".³⁶ No studies were found which directly explored women's decision-making process to use BHT.

1.7.2 Physicians' Perspective on BHT

No studies were found that examined family physicians' perspectives regarding BHT, their experiences caring for women on this therapeutic modality, or their role in women's BHT decision making process. However, a cross sectional study of pharmacists found that those who compounded BHT were more likely to believe in BHT safety, and have greater confidence with this therapeutic modality.⁵⁶

1.8 Thesis Purpose

Although researchers have explored women's decision-making process, beliefs and attitudes regarding hormone replacement therapy in general,^{34, 57-60} There remain many unexplored questions related to women's BHT decision-making process. There are also many questions regarding the role a family physician may play in that process and how the patient-doctor relationship may be affected by patients' decisions to use BHT. Given the lack of literature, an appropriate starting point is to begin by exploring the journey of women in acquiring BHT, and their reasons for using it. Secondly, it is important to

explore family physicians' experiences, perceptions, and attitudes toward this treatment modality. This thesis was designed to address these objectives.

1.9 Thesis Design

Two qualitative studies using a phenomenological approach were conducted in this thesis. It was felt that exploring women's and family physicians' BHT experiences separately would provide a deeper understanding of each groups individual, and unique experience of the phenomenon,⁶¹ and would allow for a more thorough account of their lived experience.⁶² This specific feature of phenomenology is valuable as it supports a fresh perspective absent from preconceived concepts of BHT. The studies involved in-depth interviews with women using BHT and family physicians that care for this population.

The sample size, as with most qualitative inquiry, is not guided by numerical calculations, such as statistical significance or statistical power, but rather is guided by researcher judgments about the sufficiency of the information gathered.⁶³ An adequate sample size is one that permits deep, case-oriented analysis and rich understanding of an experience that is a hallmark of all qualitative inquiry.⁶⁴ Thus data gathering in both studies occurred until "theme saturation" was achieved. That is, when no new themes were seen to emerge with further interviews.⁶³

With respect to constructing the interview guide, Thomas and Pollio suggest that interviewers must unlearn how they typically ask questions, to help draw out rich, descriptive phenomenological responses from the participants.⁶⁵ They state that "the phenomenological question is not designed to elicit a theoretical explanation or statement; hence, 'why questions' which lead individuals from description to theory are avoided".⁶⁵

They propose that using ‘what’ questions helps the researcher elicit more detail-oriented accounts of the participant’s experience.⁶⁵ Moustakas also describes two broad, general questions: What have you experienced in terms of the phenomenon? What contexts or situations have typically influenced or affected your experiences of the phenomenon? These questions focus attention on gathering data that will lead to a textual description and a structural description of the participants' experiences, and ultimately provide an understanding of the common experiences of the participants.^{61, 66} These recommendations were used to inform the design of the interview guide in both studies.

In phenomenological inquiry, multiple sources of data are preferred.^{61, 64} In an attempt to have a better understanding of participants’ experiences it is of value to consider both their verbal descriptions, as well as their physical responses to questions. Lived experiences are also embodied experiences and people relate to the world with and through their bodies.⁶⁴ Van Manen considered embodied experiences to be an important component of phenomenological reflection and a key element in understanding the lived experience.⁶⁷ Thus, field notes were recorded during, and immediately following each interview. They involved observations on, bodily gestures, facial expressions, recoiling, reaching out, sighs, and emotional responses.

In phenomenological research the concept of “bracketing” or “epoche” - in which investigators set aside their experiences, as much as possible, to take a fresh perspective toward the phenomenon under examination - is of significance.⁶¹ It is an intellectual activity, where one tries to put aside theories, knowledge and assumptions about a phenomenon.⁶⁵ It is an approach that is deemed to be an essential component of the phenomenological method.⁶⁵⁻⁶⁷ Moustakas states that merely the energy, attention and

work involved in reflection and self-dialogue significantly reduces the influence of preconceived thoughts, judgments and biases.⁶⁶ Reflexivity can be defined as “the process of continually reflecting upon our interpretations of both our experience and the phenomena being studied so as to move beyond the partiality of our previous understandings and our investment in particular research outcomes”.⁶⁸ Thus the intellectual process of reflexivity involved: thoughts on historical experiences, values and pre-understandings of BHT.

1.10 Thesis Structure

This thesis explored, through phenomenological qualitative designs, women’s and family physicians’ experiences with BHT. It aimed to develop a deeper understanding of women’s decision-making process in choosing this therapeutic modality, and the influence family physicians may have on this process.

The current chapter presented a summary of the use of hormone therapy in managing menopause, an explanation of the terminology used in hormone therapy, and the differences between BHT and conventional hormone therapy. The chapter also provided a review of the literature pertaining to women’s use of BHT to manage menopause, and the perceptions of family physicians pertaining to this treatment.

Chapter Two reports on a qualitative study that explored how women seeking menopause care reached a decision to use BHT. The women experienced significant distress in their menopause transition and desperation for symptom relief, which lead to their discovery and trial of BHT. Ultimately, the women experienced restitution and enhanced wellbeing while taking BHT. However, their healing journey was experienced simultaneously with

frustration and disappointment in the medical community's lack of support and acceptance of their treatment choice.

Chapter Three presents a second qualitative study that examined the experiences of family physicians caring for patients who were taking BHT. The family physicians demonstrated awareness of the delicate nature of the menopausal transition for women, and their role in helping overcome women's fears and apprehensions as well as mitigating their symptoms. They described concerns about BHT safety and challenges in reaching a balance between their patients' wishes to use BHT and standard practice.

Chapter Four integrates the findings from chapters two and three, and discusses the shared themes that emerged. In addition, specific policy suggestions are made regarding the journeys and decision-making process of women taking BHT.

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Chapter 2

Bio-Identical Hormone Therapy: Understanding Women's Decision-Making Process

Menopause and the peri-menopausal period are significant transitional chapters in the lives of most women. The average age of menopause (i.e., cessation of menses) is approximately 51 years, with a range of 40 to 55 years.¹ The majority of women in advanced societies can expect to live 30 years beyond this point.¹

Generally menopause is associated with varying degrees of psychological and physical symptoms. Hot flashing, and its accompanying symptoms including sweating, palpitations, apprehension, and anxiety, affect 60-80% of women entering menopause.² Although most menopausal women (60%) experience hot flashes for less than 7 years, up to 15% report that hot flashes persist for 15 years or more.³ These symptoms contribute to the woman's discomfort, inconvenience, and distress, particularly when these episodes occur very frequently.

In the past, women were routinely prescribed hormone therapy to help relieve symptoms associated with menopause, as well as for prevention of coronary heart disease and osteoporosis.⁴ Clinical practice patterns changed dramatically after the publication of the Women's Health Initiative (WHI), a landmark study that indicated an increase in the risks of venous thromboembolism, cardiovascular disease, stroke, and breast cancer with combined estrogen/progestin therapy.^{5,6} In the United States the number of annual postmenopausal hormone therapy prescriptions decreased by 38 percent in the first year after the WHI publication in July 2002.⁷ The extensive media coverage of the WHI

findings evoked significant discussion, controversy, and concern among women and their health care providers about how best to deal with their symptoms.^{8,9} Some women have chosen to use bio-identical hormonal therapy (BHT) as an alternative to conventional hormone preparations.¹⁰ The "bio-identical" approach generally refers to the prescribing of individualized doses of hormones that are delivered in pharmacy compounded creams and pills. The hormones most commonly compounded are estradiol, estrone, estriol and progesterone.¹¹⁻¹³

There is, however, very little published information about the use of bio-identical hormones, their safety, or their efficacy. Most Menopause Societies do not endorse their use.^{14,15} Further, there appears to be concern that the terms "bio-identical" and "natural" may be misleading to women, suggesting that they are safer than HRT and influencing women's decisions to use them.^{10,16-18} Beliefs that BHT are safer than HRT likely plays a significant role in women's selection of hormone therapy. Although researchers have explored women's decision-making process, beliefs and attitudes regarding hormone replacement therapy in general,^{8,19-22} there is little known about the decision-making employed by women who use BHT. Thus, studying women's reasons and journeys to acquiring BHT, as well as their experience using it, is an initial step toward addressing this gap.

2.1 Purpose

This study aimed to explore: 1) menopausal women's experiences accessing and using BHT; 2) their decision-making process in choosing this therapeutic modality; and 3) how the patient-physician relationship may be affected by that decision.

2.2 Methodology

2.2.1 Study Design

A phenomenological qualitative study utilizing in-depth interviews of women on BHT was used. This research framework provides a deeper understanding of a phenomenon (in this case using BHT) as experienced by several individuals.²³ The basic principle of this design is to reduce individual experiences with a phenomenon to a description of the universal essence of the experience.²³ This description consists of “what” they experienced and “how” they experienced it.²⁴ This understanding of the essence of menopausal women’s BHT experience may be valuable in directing suitable menopause-related counselling, and informing practices that enhance the therapeutic patient-physician relationship.

2.2.2 Recruitment and Sampling

It is essential in phenomenological approaches that all participants have experience of the phenomenon being studied²³ Thus, participants who would be able to contribute to data that was in-depth and information rich were recruited.²⁵ Women attending a BHT clinic in London, Ontario were recruited for the study. Potential participants (N=200) were identified through the clinic’s records by administrative staff and were mailed a letter (Appendix I), which described the study and invited them to participate. Women (n = 35) who responded to the letter were screened using a telephone interview to insure they experienced the phenomena of taking BHT for menopause management and met the following study inclusion criteria: (a) women aged 40 or older (b) actively taking BHT.

The exclusion criteria included: (a) BHT post breast cancer prophylactic surgery; (b) history of premature ovarian failure and menopause before age 40 years; (c) BHT post chemotherapy and or radiation therapy; (d) history of breast and/or gynaecological malignancy. Throughout the process of recruitment particular attention was paid to the following participant characteristics: age; menopausal status (i.e., peri-menopausal or post-menopausal); and prior history of HRT use. This was done in an effort to attain a maximum variation sample to represent diverse individuals and insure multiple perspectives about the phenomenon.^{23, 25}

2.2.3 Data Collection

In-depth interviews were conducted, using a semi-structured interview guide (Appendix II) between May to August 2012, at either the BHT clinic, Western University, or the participant's home; two interviews were conducted by telephone. Interview questions were structured around three main areas: (a) describing the menopausal transition; (b) describing the experience of attaining and using BHT; and, (c) understanding participant's views of the family physician's role. However, each interview was also guided by the emerging dialogue, and the interview guide was adapted as new information emerged from the data analyses. Consent (Appendix III) was obtained before all interviews. Interviews, which lasted approximately 45-60 minutes, were audio-recorded and transcribed verbatim. Field notes and reflexive journaling^{23, 26, 27} were completed during and immediately following each interview. Participants received a \$10 gift card in appreciation for participating. The study was approved by Western University's Ethics Board (Appendix VII).

2.2.4 Data Analysis

Analysis of all interview transcripts and field notes occurred through an interpretive and iterative process that included the following; (1) reading and familiarization with each transcript's overall descriptive account; (2) grouping recurring words and significant statements into a coding template that was organized in a similar manner to the interview guide; (3) generating units of information called "themes"^{23, 27} and continually expanding, and revising them as new themes emerged throughout the data collection and analysis; (4) using diagrams to compare themes across participants; (5) collapsing smaller subthemes within larger thematic units; (6) identifying exemplar phrases that captured the themes; (7) producing the manuscript. Data analysis occurred concurrently with data collection and continued until theme saturation was achieved (i.e., when no new themes were seen to emerge with further interviews).²⁵ Initially the researchers (LW, GR, AT*) individually and independently read each verbatim transcript. The researchers subsequently met on a regular basis to compare and combine their independent analysis, and to synthesize the data in a comprehensive and agreed upon description of the essence of the phenomenon. Techniques used to promote trustworthiness and credibility of the data involved: 1) purposeful screening to ensure all participants experienced the phenomenon; 2) maximum variant sampling to enhance the capturing of varying perspectives of experiencing the phenomenon; 3) audio-recording interviews, verbatim

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transcribing and detailed field notes to maintain methodological rigor; 4) team analysis and reflexive journaling to maximize researcher transparency; 5) constant referring back to the data for verification of emerging themes to ensure applicability of the analysis to the context of events.^{25, 28}

2.3 Final Sample and Demographics

After respondents were screened using a telephone interview, a total of 32 women met the study criteria. Participants were selected for interviews based on maintaining a variation in their age; menopausal status (i.e., peri-menopausal or post-menopausal); and prior history of HRT. Maximum variation and theme saturation were achieved by the twelfth interview. Only data for the 12 participants are described. Participants ranged in age from 54 to 68 years of age (mean = 56 years). The majority (n=10) were post-menopausal (i.e. had not had a period for 1 year or more) with a mean of 10 years since their last period (range 2-25 years); two women were peri-menopausal. Few (n=5) women had hysterectomies. All participants were Caucasian. The majority (67%) were married; 33% were divorced or separated. Two thirds of participants had a college degree or higher level of education; the remaining one third had completed high school. The annual income of most (75%) participants was \$40,000 CAD or higher; 25% had an annual income of \$20,000-39,999 CAD.

Half of the participants had taken HRT in the past; only two had made a direct transition from their HRT therapy to BHT. Women in this study were taking BHT for a mean of 2.5 years, with a range between 3 months and 8 years. Six women were taking a

combination of three hormones (testosterone, estrogen and progesterone), one was taking progesterone only, and the remainder were taking an estrogen, progesterone combination.

2.4 Findings

Analysis of the data revealed five inter-linked themes which describe the essence of the women's BHT journeys: a) transition into menopause; b) quest for symptom relief and restitution; c) decision to use BHT; d) experience using BHT; and, e) the patient-physician relationship through the journey. Participants reported experiencing distress during the menopause transition and described chaotic accounts of suffering, confusion, helplessness and isolation, resulting in a sense of desperation that fuelled their incessant quest for relief. They described an experience of restored well-being and a regained sense of normality on BHT. Although their healing journey was one of victory, it was experienced simultaneously with frustration and disappointment in the medical community's lack of support and acceptance of their treatment decision.

2.4.1 Theme 1: The Transition into Menopause (Menopausal Turmoil)

The transition into menopause was a very difficult time for most of the women in the study. The impression of chaos and turmoil were predominant in the findings, and appeared to have four elements: suffering, confusion, helplessness and isolation. These elements were not isolated to the menopausal transitional period alone, but were also inter-woven throughout the women's journey to their restored well-being. They contributed to an underlying current of desperation that was the catalyst to their relentless search for relief.

2.4.1.1 Suffering

The participants suffered as a result of unremitting symptoms and their consequent social implications. They described their menopause transition as being “horrible” and “unsettling” or even feeling “under assault”. Most women felt their symptoms overshadowed all other aspects of their lives:

You can’t be prepared for the cloud; it’s like a gray cloud. You’re living under a gray cloud and even though maybe the sun’s shining on days, you couldn’t get excited about it ... it really zaps you of your spirit!

All of the participants reported experiencing similar clusters of physical and emotional symptoms. The most commonly mentioned and disturbing symptoms were hot flashes, night sweats and sleep disturbance:

The hot flashes were just horrendous! I would be awake 10 times every night with drenching night sweats, drenching to the point I have to change my pajamas 10 times every night. I had to blow dry my hair two or three times every night because my hair was soaked ... It got to the point that I thought I was going to go nuts!

In terms of emotional symptoms participants told stories reflecting how difficult it was for them to cope with day to day life:

I felt at times that I was actually dying. I would really say that. I really felt that poorly about myself. I think I got depressed because I wasn’t sleeping. When you’re up every hour through the night, I was dragging through the day. I wasn’t a nice person to be around. I just didn’t feel well. I didn’t feel well at all.

The suffering of the participants in this study was not only related to their physical and emotional symptoms, but also by the impact they felt their condition had on their family and their vocation. The majority of participants expressed feelings of guilt towards family members who endured the transition alongside them. They also contemplated making major changes in their work load to accommodate menopause “certainly ending

my job and thinking I'm just going to have to take it easy, I can't keep working and [should] not take on any kind of anything".

2.4.1.2 Confusion

Participants' expressed confusion as part of their menopause experience. Many women were not sure if their symptoms were menopausal in origin, or if they were a result of life stressors, or another medical condition:

I also went into a deep depression, and that's where it got confusing for me, I didn't know if I was having mood swings because of the menopause or the depression, or ... because I was raising a teenage daughter by myself, or ... because I'm still going through the divorce.

Even though women in this study sought medical help from their family physicians, many felt they did not receive a clear diagnosis of menopause, which added to their confusion - "I don't know if I'm even there yet. Nobody's ever came out and said, "Okay, you're now full blown menopausal."

2.4.1.3 Helplessness

Helplessness was a predominant aspect in the participant's transition into menopause. "You can't help yourself. You feel really helpless!" This was primarily rooted in their sense of losing control as a result of unmanageable symptoms. The trial of multiple failed remedies contributed to these feelings:

I tried wild yam cream ... Primrose oil ... many pills... I didn't find they helped at all ... Diet was the big thing too. You know, eat healthy and exercise and you won't feel a thing. Well, that's not true!

If they made it, I tried it! ... The doctor put me on the pill and that was bad, bad, bad. I ended up with yeast infections. He put me on premarin, and that caused

yeast infections ... He put me on depression medication and I didn't like it at all [I felt like a] Zombie.

On the other hand, many participants reported being urged by health care providers to tolerate their symptoms under the premise that menopause was a natural process that did not require intervention. Those encounters appeared to have a discouraging effect on the women and exacerbated their sense of helplessness:

What made [menopause] really awful was that I was trying to get help and I just felt like nobody was helping me! I'm going to these doctors and I'm thinking shouldn't they be able to help me?... if he can't help me then I need to go somewhere that can ... it gets frustrating.

2.4.1.4 Isolation

The majority of participants spoke of a great sense of isolation as illustrated by the following quotes:

I felt so removed from everybody that I thought I was looking through a screened window, looking down at everybody else as they were carrying on their day.

I sort of retreated from everybody because I was angry inside and not feeling well, but nobody seemed to really understand what I was going through. So rather than getting in a lot of conflict, I just sort of withdrew from everybody.

[Menopause] made it very difficult for me to work. It made it difficult to get along with colleagues. It made it difficult to get along with my family, my children. It gave me a sense basically that I didn't give a shit about anything! I just wanted to socially withdraw, to turtle.

Feelings of isolation were compounded by a lack of understanding from family and friends and a lack of sympathy from medical professionals:

This was really important that I was going through and it didn't get the attention that it needed. He [family physician] minimized it!

2.4.2 Theme 2: The Quest for Relief

A predominant subtheme that emerged was that of desperation. It appeared to surface from the relentless symptoms and resulting turmoil women were experiencing during their menopausal transition “I was at that point I was ready to try anything ... I was grasping at straws”. Desperation was the primary driver behind the participants’ unrelenting search for relief, and their willingness to experiment with different remedies. “I needed to find something to solve my problems; I was on a quest to find something that works for me.” The participants’ active search can be divided into three distinct steps: an initial general exploration of any therapy that may be beneficial, the discovery of BHT as a therapeutic option, and finally a focused search for a BHT provider (see figure1).

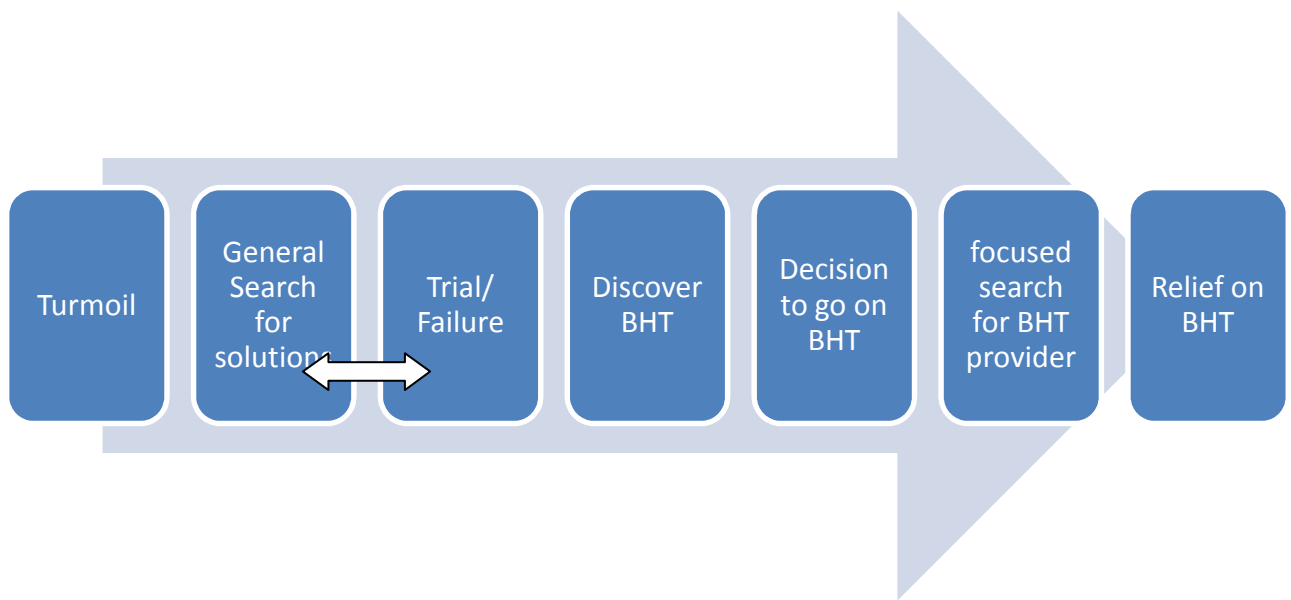


Figure 1: Women’s Menopausal Journeys

2.4.2.1 First Step, General Search

Although the search for “anything that works” was pervasive among participants, two clearly distinct groups emerged: women who were willing to try anything, including HRT, and women who were interested in only trying any natural remedy.

Participants who sought natural treatment options had some degree of aversion to prescriptive drugs and conventional medicine “I divorced the western conventional medicine theory with a number of things years ago.” This group reported being principally concerned about the safety of the pharmaceutical HRT as a treatment modality:

... because of all the stories I’ve heard on the pharmaceuticals, I chose not to do them and to try anything that’s natural, because I feel a little bit safer with natural products.

Participants who were open to HRT felt their family physician’s support and encouragement was an important factor in persuading their decision to try HRT. Women in this group commonly felt significant symptom relief and would have been content continuing on HRT. Many women in this group described being urged by their family physicians to discontinue HRT after the publication of the women’s health initiative (WHI) study^{5, 6}:

I tried to go off [HRT] for a while ... when [the WHI] study first came out. So I said to doctor [name], “Okay, I’m going to try and go off [HRT]. I went off for several months. I just felt wretched! I mean just awful! ... I went back to not being able to sleep... [Hot flashes] were every half hour. I persevered for a while and then I went back [to my doctor] and said, “Look, this is not working for me!” And again, we have the discussion about quality of life as opposed to quantity... so I went back on [HRT].

Regardless of the participants’ management preferences, many experimented with a multitude of natural and pharmaceutical therapies including: vitamins, herbal supplements, life style changes, diet, oral contraceptive pills, and anti-depressants. Many of these therapies were not effective in relieving their symptoms. The repeated failed trials of various remedies reinforced the women’s desperation and contributed to the sense of chaos in their menopausal transition.

2.4.2.2 Second Step, Discovering BHT

Most participants discovered BHT through word of mouth. The act of other women sharing information about BHT with them reassured and encouraged many participants to explore this modality:

A lot of it I think is word of mouth. When the girls get together and do their chit chats you learn so much. Even things that you're scared to pursue, when you're amongst friends and you talk, it's easier to learn and find out about things.

Testimonials and observing friends' or family member's symptoms improve while on BHT were strong factors in influencing women to try BHT. Yet most participants read up on BHT before moving on to the third step of their active quest, a focused search on finding a suitable BHT provider.

2.4.2.3 Third Step, Focused Search

Once women established that they were going to try BHT they were determined to find a suitable practitioner; however this was a challenging process:

I want to explain to you how difficult it was finding a doctor that would provide bio-identical hormones ... I researched online and the only doctors that I could find, one was in [city-X] and one was in [city-Y]. So I decided just [based on] traffic, it was better to go to [city-Y] ... You can imagine, you start having some issues and you have to go all the way into [city-Y]

Participants usually identified a suitable BHT practitioner prior to approaching their family physician for a referral:

... I went to my family doctor and I said: You know, I can't tolerate these symptoms anymore ... I went to my family doctor because I want to see doctor [BHT provider] and he usually will go ahead and follow through on things that I want ... Even though he's not quite convinced about the seriousness of it, but he will do what I ask or request, I guess.

2.4.3 Theme 3: Decision to go on BHT

Decision making for the majority of participants was a nonlinear process that predominantly occurred during the second and third steps of their quest for symptom relief, and involved the following four components: a) evaluation, b) resolve, c) reinforcement, and d) conflict.

2.4.3.1 Evaluation

Many participants researched BHT prior to deciding to use it. Media sources were the resources most often used including both written material (i.e. magazines and books) and television shows. Books by a popular celebrity promoting BHT were unanimously mentioned by women as a very educational source, even though the majority did not believe celebrity endorsement was a valid resource:

...I also read the Suzanne Summers book where she talked about [BHT], and I was going “oh my god, that’s me, that’s me right there”. So I pursued it, and I decided to go to my doctor and get a referral.

Searching for information on the internet was frequent among participants and was considered to be a more reliable source than media based references:

First I read Suzanne Summers book that was my first step... and then of course I’m looking at it like really? Because she’s a flake as far as I’m [concerned] ... then I just looked it up on the internet.

Another common resource was books by naturopaths or herbalists. Other participants relied on medical sources of information. They turned to their pharmacist and BHT practitioners for information. “... The only sources I’ve really used are the pharmacists and the [BHT] doctors.”

2.4.3.2 Resolve

The impact of testimonials and word of mouth were powerful forces in influencing the decision making process. However, a constellation of internal and external factors also had a major role in persuading participants to reach their final decision of going on BHT. Those factors included an intermingling of internal beliefs and attitudes about health care, that were reinforced by the external information (e.g., books) they had found on BHT, which were further supported by the women's perceptions of BHT's safety. Many women in the study appreciated the philosophy of BHT and found it "made sense". They believed that there were no concerns in using BHT, as the source of the hormone production was plant based, and also believed it to be more natural as exemplified in the following statements:

What I very much like is the naturopathic sense of it. I'm not plagued with the thoughts, if I may put it that way, plagued with that sense of risk and side effect.

When I'd heard that these things [BHT] were at least plant based, I thought "Okay I'm going to go for that" ... I figure if they can make something that works for me and it's from a plant, it can't be that bad.

I would have taken anything, honestly, to just stop the symptoms. But the idea... that these things [BHT] ... are matching the body and are actually good for the body ... I was willing to try that. It sounded better to me than the pharmaceutical, just because it seemed natural.

Even though most participants felt BHT was a reasonably safe treatment option a significant number of women voiced their concerns about risks and evaluated their own personal histories in determining the suitability of this treatment for them:

First of all, I don't have a uterus so there was no problem with the cancer of the uterus. And, that was more with the premarin and provera or whatever those were called. I think with estrogen, there's the concern with breast cancer, and stuff like that. Again, there's none in my family. I looked at the risks and I said it was definitely worth trying.

Others felt that the severity of their symptoms justified taking a risk. “There hasn’t been a lot of clinical studies done as far as bio-identical and cancer that I’m aware of ... but my benefits outweigh those risks”. But many felt that even though there might be some risk with BHT is was far less than conventional HRT. Many women spoke passionately about their right to chose:

I think it’s the same as any woman; you make an informed choice to take the risks or not take the risks ... so you make a decision and you think okay “I’m going to take those risks. I’m going to take those because I am not going to be miserable” ... If it’s a choice between being miserable and taking the risk, I’m going to take the risk...I don’t believe in misery.

The hope for symptom control was the main purpose women started BHT:

I was just hoping that this would help because basically my doctor said there’s not a whole lot else out there ... when I found out about this [BHT] I’m like, oh my gosh, maybe there is something out there...that can help.

2.4.3.3 Reinforcement

Starting BHT considerably improved menopausal symptoms for the majority of participants. Symptom improvement was the primary reason for their satisfaction with BHT, and a key factor reinforcing their decision to use it:

Because I had experienced the natural progesterone cream and how well it worked, without any negative side effects, I was willing to try the estrogen and testosterone ... without hesitation.

Many women felt transformed by BHT and statements like “Bio-identicals absolutely changed my life, I feel better now than I have in my whole life!” and “It gave me my life back ... it saved my life!” were frequently reported.

The dramatic symptom response had a resounding effect on the participants' commitment to this treatment modality. Many women declared "I wouldn't be without them", had strong desires to advocate for its general availability, and were empowered to educate other women about it.

For about a year I was telling every woman I knew that you can get some relief ... Now that I'm on bio-identical hormone creams, I said, I feel like my old self.

I would highly recommend [BHT], now that I've [been on it], I'm very comfortable with them ... And now after seeing it helping me for the last three years, I would highly recommend it.

2.4.3.4 Conflict

Many participants were conflicted by their thoughts about the long-term safety of being on BHT and their fear of symptom recurrence if they discontinued it. As a result, women in this study did not have a set plan to stop BHT at a specific point, and were not able to project how long they would continue on it. There was a common belief among participants that their BHT practitioner would guide them to the appropriate timing of when to consider discontinued BHT use, yet the majority preferred to not think about that possibility and had decided to continue on them as long as possible.

I will stay on it. I'm afraid to go off. I really am! I'm afraid to go off hormones ... I feel that if I go off of bio-identicals, I will have all my symptoms back and that scares me ... So I will stay on it as long as I can.

Will I stop them soon? No, not on your life! I said I'm going to give up food before I give up my bio-identicals.

Some women in this study approached this conflict through their intention to periodically re-assess its need and safety.

... I wish there was maybe another 20 years of research on it. I feel like I'm part of the guinea pig group, which is okay. The alternative of going right off of everything doesn't sound very pleasing ... I'd like to take it five years at a time ... I mean if I can stay on them for all of my life and they are said to be safe, I will! But because it's so new, how can they say that really? So in my mind I'm thinking, well, I'll judge for five years, If everything seems fine and I'm still able to do all the things that I want to do.... I figure I'd rather take the chance that there are some risks, if there are any risks, than go back to not being able to do anything.

2.4.4 Theme 4: The Experience of Being on BHT

Most of the women in this study experienced a significant reduction in their menopausal symptoms while on BHT. They reported dramatic responses with symptom relief that appeared to be directed to the women's own individual and most bothersome complaints:

I'd have trouble going to sleep, I'd have trouble staying asleep, I'd have trouble sleeping in the morning ... Now I go to bed at night, I fall right to sleep; I stay asleep until my alarm goes off in the morning.

The hot flashes, after a few weeks, were starting to decrease. It wasn't like bang the first night or anything but within a few weeks, I did notice they started to decrease in intensity and severity.

I was bleeding about every 11, 12 days ... today, I'm bleeding once a month which is stunning to me, It's just stunning!

Women felt their symptom reduction was rapid, and reported a range between 3 days and four months to achieve satisfying symptom management. Many were astonished by their response and were elated at their restored health. Women talked about regaining a sense of normality, "This is the first time I feel normal again"; retrieving their old selves, "I feel like I'm back to the person that I was years ago"; and recapturing their womanhood, "It just makes me feel like a whole woman again". Many women described their symptom relief as "a weight being lifted".

Within the first month of using [BHT], it's like a huge cloud gets lifted, fog gets lifted. You can see clearer, you can sleep better everything is better! It's like looking through clean glasses.

The main drawback reported by most participants was the expense of BHT as it was generally not covered by most of their health plans. Yet, women expressed their intention to continue using BHT regardless of cost and expressed frustration that it was not readily obtainable:

I don't like the cost of it. The price is a little bit high, but I'm willing to starve to get my bio-identicals!

It's covered on my husband's plan. Maybe one day it won't be covered on his plan, but I'm going to make sure I get it any way. I'm going to factor it into the cost of living.

You know for a lot of women they wouldn't be able to afford it. And I think that's unfortunate ... because I think it's an aid to better health and good living. I don't feel that it should be a luxury! I think it should be available to people who need it.

In summary, participants' desperation for menopausal symptom relief was the primary driver behind their search for a remedy. This search reached an end with the discovery of BHT and the positive experience using it. Despite the obstacles in obtaining BHT and the mixed views on the safety of this modality, participants decided to continue its use and declared it to be their ideal therapeutic choice.

2.4.5 Theme 5: Menopause and the Patient - Physician Relationship

Exploration of the participants' reflections on the relationship with their family physician throughout their menopausal journey revealed two distinct stages. Stage one, before discovering BHT and stage two, after discovering BHT (see figure 2). This section describes these themes in detail.

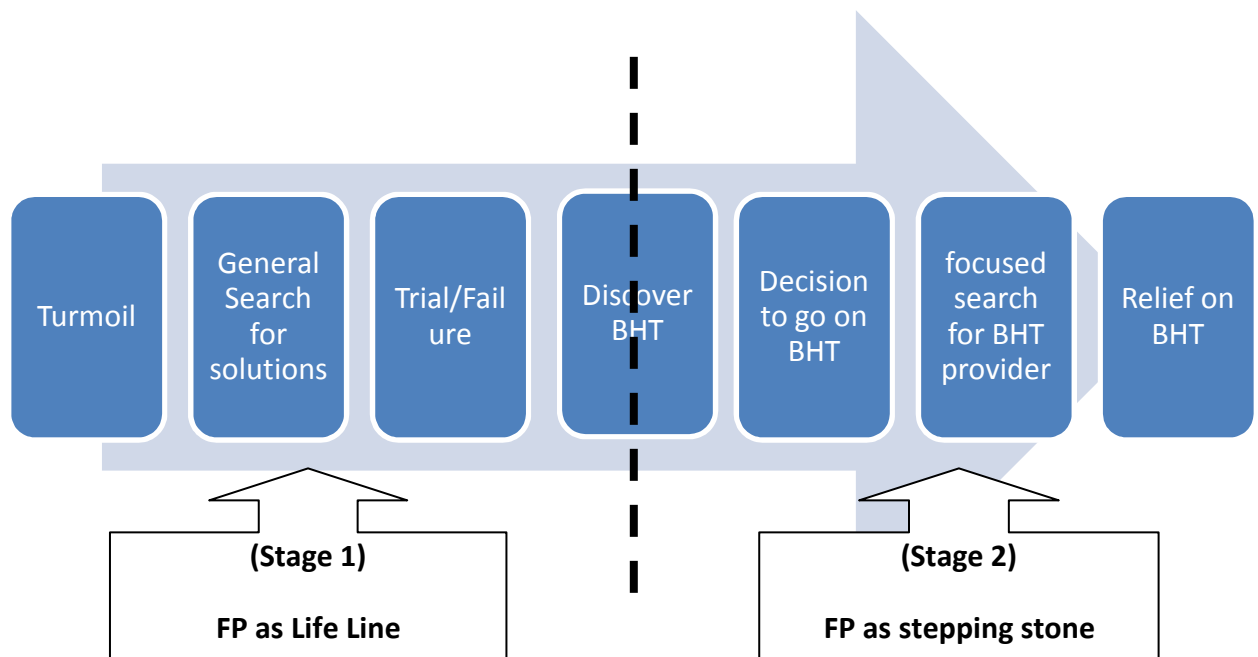


Figure 2: Family Physicians Roles throughout the Women’s Menopausal Journeys

2.4.5.1 Stage One, Family Physician (FP) as Life Line

This stage encompassed the participants struggle with menopausal symptoms and resulting turmoil as well as their relentless search for relief prior to discovering BHT.

Women during this stage appeared to turn to their family physicians with hope for help and support during the hardships of their menopausal transition. There were three factors which emerged and were believed by participants to be pivotal to their health care during this life transition, and essential to maintaining a satisfactory relationship with their family physicians thereafter. These factors were: (a) the physician’s realization of the significance and vulnerability of menopause; (b) anticipating and preparing women for possible symptoms during this evolving period; and (c) providing women with therapeutic choices and management options.

2.4.5.1.1 Menopause is a Significant Time

All participants in this study felt that the menopausal transition was a very important time in a woman's life, yet one that did not receive the attention it deserved. "Women are being ignored! It's a great injustice". Many women were expecting their family physicians to play a central role in helping normalize their experiences and in working with them to achieve a healthy transition.

... There are many big stages [in life] and [menopause] is one of them. I'd like to know that my doctor would take great interest in following along with me and encouraging the positive or the healthiest side of [this stage].

Participants believed family physicians should consider the generational change in women's roles as an essential feature in understanding the impact menopause has on women today.

I think [doctors] should be much better informed about the comfort level of women, and the fact that women are not dying after they've had their last set of children any more. Things have changed, and [doctors] have to look at things very differently... They need a more informed approach to the ageing process, the comfort level of women, and the fact that women are in the workforce much later... than they were years ago. ... Some family physicians still have the view that it's a natural process. Well maybe it's a natural process, if you're going to die a few years afterwards. But even then, I don't think you need to be miserable for those few years. I think comfort is very important.

Participants identified that having a family physician who listened to their concerns was vital to building a trusting therapeutic relationship:

I tried to talk with my family doctor about my menopausal symptoms, but he sort of brushed them off. ... That was sort of [a] communication barrier ... I went ahead and referred myself to the women's health clinic ... to see if they could provide me with any more information about menopause.

Part of being heard was being given sufficient time during clinic visits to explore issues, and being asked questions which suggested to participants that their physician was interested in the impact of menopause on their lives.

I really think they need to ask how [you are] feeling, because when it's happening to you, you're lost!

On the other hand, many women felt they were being heard by their BHT provider, and thus better cared for.

The gynaecologist and my family doctor wouldn't even take the time of day to talk about menopause or what's available. And in this situation, somebody [BHT provider] listened to me. That's a big difference.

A central feature of a positive patient- physician relationship repeatedly described by participants was having a family physician that was compassionate and understanding. It was also considered to be a key factor in feeling heard and cared for.

2.4.5.1.2 Prepare Women for Menopause

Women in this study took responsibility for their own education related to menopause. However, they also emphasised the necessity of family physician-directed education, and the role that physicians have in preparing patients for possible symptoms during menopause:

I feel that [family doctors] have a responsibility to provide women with a fairly comprehensive description of what happens, what to expect in menopause, what's causing it in menopause, and perhaps, in some cases, even have the husband or partner come in at the same time so that everybody knows what's going on.

This anticipatory approach to menopausal care was believed by many participants to be reassuring with the goal of there being no "surprises". Women felt such an approach would reduce their anxiety in response to new physical and emotional symptoms.

This approach was also considered to be vital in overcoming communication barriers such as embarrassment in bringing up symptoms with male physicians. Having a male family physician was considered by some women to be an obstacle in their menopausal care.

This was either due to feelings that a man would not be able to appreciate the significance of their symptoms as well as a woman would, or due to the woman's hesitancy in bringing up complaints related to their reproductive system with a male physician. The women who did discuss their symptoms with male physicians expected their physicians to overcome any gender disadvantages by expanding their medical knowledge of women's health issues. Women also stressed the importance of an enhanced awareness of the spectrum of menopause symptoms and its differing impact on women.

I think that a family doctor, whether male or female, should be very educated. Not just thinking that a woman's going through menopause, she's going to have irregular periods, hot flashes, brain fog, and night sweats and that's the same for everybody. It's not the same for everybody ... Not everybody can be put in the same mould, everybody's different.

In general, women felt it was the physician's responsibility to initiate the menopause conversation. When asked what physicians could do to better help women going through menopause, many participants suggested physicians participate in public and wider spread methods of initiating the menopause conversation and education. For example, women suggested that physicians organize seminars, where women could freely talk about their menopause journey. Pamphlets and hand outs on menopause were suggested by other participants as a method physicians could utilize to open the discussion:

If [doctors] don't have time to discuss [menopause], then they should have a hand out of some sort that you take it home, you read it ... [and then have] a discussion afterwards.

2.4.5.1.3 Provide Therapeutic Options

The deficiency in therapeutic options offered by family physicians was an additional missing factor during stage one (family physician as life line), raised by participants.

Many women hoped for a more holistic approach to menopause management that involved life style recommendations as well as available pharmaceutical and non-pharmaceutical remedies. Participants also expected to have an open conversation with their family physicians on hormone therapy risks and benefits:

What are all the options, what healthy habits can a woman engage in to assist with menopausal symptoms, and to alleviate them? ... “Okay you want HRT? These are the risks and benefits, based on your family history or based on your medical history”...

Many women felt their physicians did not ask them enough questions about their menopause experience before prescribing a treatment. On many occasions, the lack of symptom exploration resulted in scepticism about the appropriateness of the treatment prescribed.

I don’t really think that I should be put on an anti-depressant. I think we should be finding out if these symptoms are menopausal, or if there’s something else causing it, before I go on anti-depressants.

In addition, participants who were prescribed medications that did not work felt discouraged and abandoned by their family physician.

They need to send you to somebody who they think can help you. If they feel that they can’t, that [HRT] is the only thing that they can do, and if [it] doesn’t help, [then] “I’m sorry I can’t help you”. That’s a horrible thing to hear.

Alternatively, some women felt they were not allowed to make their own choices, due to their family physicians fear of HRT risk. Some participants described frustration with their family physician’s paternalistic approach.

Keep up with the information on the research and let your patients know about it, but give them the choice after that. Even have them sign a paper saying, “My doctor has explained to me the pros and cons and I have chosen this route, even though it could be detrimental to my health in the long run.” I think taking the responsibility off that way would be a good thing because I’m sure he’s very

responsible and I understand his concerns and his position, but, give the responsibility back to the patient who's made the choice.

Overall, participants valued discussing their therapeutic options with their family physicians and would have liked to explore complementary and alternative therapeutic modalities with them.

I think that [family physicians] should be open to the different avenues that are out there for women, not just say 'Well here's some HRT'.

Regardless if the participants' experiences in the first stage were positive or negative; all participants could be described as having transitioned into a second stage, in which they used their family physician to access BHT.

2.4.5.2 Stage Two, Family Physician (FP) as a Stepping Stone

The next stage in participants' journeys was characterized by being on a mission to get a referral to a BHT provider, or a prescription for BHT. The family physicians' role was quite limited to either facilitating or impeding their ability to get BHT. The family physician was seen as a facilitator if he or she expressed openness to the BHT modality, sent a referral to a BHT provider, and supported the woman's' decision to use BHT:

When I talked to him [participant's family physician] about what I learned and what I need, and I need a referral, I knew what doctor I needed to come to, he was more than willing to help me get to that next level. And anything new that I find out or need, he's very willing to help me get there. He's very open. He's not one to squash anything!

The women in this study appreciated a non-judgmental acceptance of their choice to try BHT. They predominantly valued the openness of the physician to this treatment modality – a quality that was considered to be vital to forming and maintaining a satisfying patient-physician relationship. Many participants were accepting of their physicians' lack of BHT knowledge and did not consider it to be a major obstacle, as long

as the physician was still open to exploring BHT with them, as demonstrated by the following participant's response to the question: "What were you looking for when approaching your physician with BHT?"

I suppose knowledge, to a certain degree ... maybe at times I've often felt that maybe I'm almost kind of educating them to a small degree. I just I wanted very much an acceptance! I wanted very much an open attitude, an open-mindedness.

When physicians were not supportive of their patients' interest in BHT, participants thought that the lack of physicians' BHT knowledge may be a significant factor in their discomfort with this modality and an issue that could prevent them from being open to talking about it. Family physicians were seen as a barrier to accessing care if they were closed to the idea of BHT.

Maybe this is something that they're not really open to, that's the feeling that I got. They're not open. It was just like, yeah, and a roll of the eyes! ... My girlfriend's ... doctor absolutely refuses to write a referral to [BHT provider's name]. We're trying to tell her, go to a walk-in clinic. She's suffering a lot and her doctor, who is a woman, says no! ... That's not fair! Just because the doctor doesn't believe in it, doesn't mean that we should have to be prohibited from having bio-identicals because our family doctor isn't on board.

The significance of the physicians' openness to BHT was so striking that some women continued to be unsatisfied even after their family physician referred them for BHT. Some participants felt so strongly about their physician's openness to alternative treatment choices that they chose to end their therapeutic relationship with their physician.

... I knew I needed to find another family doctor ... there was one who was taking new patients. I filled out the form, and on the form I said I'm very interested in bio-identical hormone therapy. So if you're not, then I need to find someone else!

Interestingly, in most cases the family physicians' role continued to be restricted to patients' non-menopause health care while they were on BHT. That appeared to be either a result of the physician's withdrawal from that aspect of their patients care or due to the

patient's choice to separate their family physician from their menopause and hormone therapy. The latter emerged as a direct effect of negative patient-physician interactions.

He's become a non-entity. I only go to him for orthotics, nothing usually more important than that. I don't go to him for anything important because this was really important that I was going through and I didn't get the attention that I needed. He minimized it! So I went to other people that were more understanding. So now, I don't waste my time talking to him about it. I just go to the ones that helped me to begin with.

There were many reports of disjointed health care among participants, with the physician's lack of interest in their hormone therapy as a repeatedly cited reason:

I would still go back to her if I felt I had an ear infection or whatever, for anything that I would think I need an MD doctor. But as far as hormones, no! That won't be discussed because she made it quite clear to me she's not interested in helping me in that area at all. She was very, very definite.

Women also interpreted the absence of their physician's curiosity about their BHT therapy as a disinterest in their general menopause care. In fact, some were upset at the loss of their family physicians involvement.

He should be interested; he should ask questions ... He doesn't even ask me, he doesn't ask me anything about them when I go to see him. He doesn't say, "Oh, I see you're on bio-identical hormones. Are they working for you? Do you think about this? Do you think about that?" But he does not ask me a thing.

Thus, having family physicians that were open to BHT and interested in their BHT experience made participants feel valued and cared for.

2.5 Discussion

This section will discuss five prominent themes with regard to understanding menopausal women's decision and experience using BHT, and the journey that led to that therapeutic choice as well as offer family physicians some relevant clinical recommendations. These themes include: a) the transition into menopause; b) quest for symptom relief and

restitution; c) the decision to use BHT; d) experience using it; and e) the patient-physician relationship.

2.5.1 The Transition into Menopause

Participants reported distressing experiences of menopause that resulted in desperation and feelings of living in chaos. The distress they experienced during this transition was strongly linked to suffering abrupt, persistent, and severe emotional and physical symptoms. Similar to other research findings, the majority of women in our study described hot flashes, night sweats and sleep disturbance to be the most frequently experienced symptoms and the most distressing.^{29, 30} Vasomotor symptoms (including hot flashes and night sweats²) are the most common menopausal symptoms to prompt women to seek care.^{31, 32} The severity of vasomotor symptoms has been linked to lower levels of health status, reduced quality of life, and a decline in overall work productivity among menopausal women.^{31, 33-36} Participants in our study spoke of similar difficulties in managing work and other daily responsibilities, and had contemplated significantly reducing their work load to accommodate their functional decline.

Participants also described a sense of “loss of control” which enhanced their symptom severity and contributed significantly to their distress, which is similar to other studies.³⁷⁻³⁹ Feelings of confusion, isolation, and helplessness were pervasive among participants, and further impacted their social and occupational lives. Similar descriptions of alienation, trivialization of symptoms, lack of support and confusion have been reported in many qualitative studies, and have been linked to descriptions of distress.⁴⁰⁻⁴² Since a small proportion of symptomatic menopausal women seek health care,¹ and women who experience severe symptoms are the ones who tend to seek medical management,^{19, 43}

family physicians need to realize the significance and impact of menopausal symptoms on women seeking care. Proper attention and support by family physicians is critical in managing menopausal women's needs and alleviating their distress.

2.5.2 Quest for relief

A sense of desperation was the primary factor that drove women in this study to a relentless search for symptom relief. The initial general search for “anything that works” was pervasive among participants. An online survey of 1663 women found that 80% of women wanted to try natural supplements before starting HRT;⁴⁴ in this study, and others, the reasons for trying a natural therapy included: feeling that it is more natural than HRT, and concerns about risks associated with HRT use.^{44, 45} Similarly, participants in our study experimented with multiple natural supplements but many also tried prescription medications. Yet participants did not find much benefit from either the natural supplements or the prescription therapies which reinforced their desperation and propelled their search for a suitable solution until they found BHT.

BHT was “discovered” by the majority of women in our study through “word-of-mouth”, mainly from friends and family members. Social support networks, including friends, partners and family members, are repeatedly cited in the literature as an important resource for women faced with menopause-related decisions in general.⁴⁶⁻⁴⁹ Social exchange of information has also been specifically identified as a prominent supporting factor in women's interest to use BHT.⁴⁶ Reaching a state where they were willing to try BHT was a prominent turning point for menopausal women in this study. BHT signified a more hopeful outlook to menopause, as women were empowered to take control of their health care, and were determined to satisfy their intention to try BHT.

Once women in our study discovered and intended to try BHT, they then focused their search on finding a suitable BHT provider that would help them access BHT. Our findings of this step wise approach to accessing BHT is supported by a qualitative study that explored women's pathway to accessing BHT⁴⁶ Women in that study reported barriers to accessing BHT that included; limited knowledgeable providers, physician reluctance to support BHT, and cost. ⁴⁶ Participants in our study reported similar obstacles in accessing BHT, which resulted in significant frustration with the medical community.

Family physicians caring for women seeking BHT need to be aware of the dramatic shift that occurs in a woman's overall menopause outlook when intending to try BHT. The intention to try BHT, based on this study, appeared to occur at the end of a struggle for symptom relief and was linked with a regained hopefulness in symptom resolution. Thus, attempts by physicians to explore the women's reasoning for choosing BHT might be seen as attempts to deter its access. Family physicians need to approach this request with caution and with compassion to avoid any possible negative impact on the patient-physician relationship.

2.5.3 Decision to go on BHT

The decision to go on BHT for the majority of participants in our study was a multi component process with four identified components: evaluation, resolve, reinforcement and conflict. The process did not always occur in the order listed and participants repeatedly assessed and modified their commitment to each component. To our knowledge there are no other studies that explore women's BHT decision making process. Studies have found that decisions regarding menopausal symptom management

in general, as opposed to the use of BHT specifically have been found to be complex, highly individual, and to follow a non-linear iterative course that can be emotionally laden.^{8, 19, 49-52} Women's decision-making process to use HRT has several stages that involve considerations of need, information seeking, weighing benefits and risks, applying beliefs and values, and interactions with social networks.^{19, 49, 51-53} In our study, women approached their BHT decision-making process in a similar manner.

Once being introduced to BHT, and contemplating the idea of trying it, participants proceeded through information-seeking to evaluate BHT as a therapeutic option. Studies have identified engagement in information seeking behaviour to be one of the initial stages women perform when making medical decisions.^{47, 52} The intention behind this initial step is to understand menopause and gather sufficient information on treatment options to make an informed choice.^{47, 51, 52}

In our study, the main information sources utilized by participants were media sources of information including magazines, books, television shows and the internet as well as social supports. Multiple studies have identified media and social sources of information to be more influential during women's menopause management decision-making process than formal sources like physicians and other health care providers.^{8, 19, 46, 49, 51} This, in part, has been linked to an increased desire by menopausal women for guidance on the use of alternative therapies and hormone treatment that is not fully met by physicians' preparedness to provide this information and guidance.⁴⁵ In addition, many women have lost trust in medical recommendations since the publication of the WHI.⁵⁰ However, information gathering and evaluation are not the primary deciding factor in women's

intention to use hormone therapy; personal values and beliefs, along with past experiences, also shape women's decision-making process.^{47, 49, 54}

Participants in our study recognized multiple internal and external factors that influenced their choice and their resolve to use BHT including: beliefs that BHT was a more natural approach to menopause management, and being reassured by the lack of documented risk. Three studies that looked at women's use of BHT support our findings of their beliefs that BHT is more natural and less harmful than HRT.^{18, 55, 56} However, a significant number of participants in our study did report concerns about BHT's safety, primarily related to the safety of long-term use. Participants were conflicted by concerns regarding the long-term safety of being on BHT and their fear of symptom recurrence if they discontinued BHT, especially after experiencing significant symptom reduction on this therapy. Although some women chose to periodically re-evaluate their need for BHT, the majority decided that their improved quality of life justified taking the risk. This can be explained to some degree by the subjectivity –relying on intuition and gut-level feelings– involved in menopause related decision-making.^{19, 51} In addition, experts are concerned about women's possible misinformed understanding of BHT safety, and the role that this understanding plays in influencing their decision to use or stay on it.^{10-12, 57, 58} The influence of women's perceptions of BHT safety on their decision-making process is an area that warrants further research. Such studies could aid family physicians in providing appropriate counselling to women on BHT that would also maintain a strong therapeutic patient-physician relationship.

2.5.4 The Experience of Being on BHT

Women in our study reported immediate, significant and dramatic reduction in menopause symptoms after starting BHT. Many were astonished by their response, and were elated at their restored health and over all regained sense of wellbeing. Similar accounts of improved quality of life, restoration of emotional and physical balance, as well as renewed optimism and exuberance for life, have been reported in one previous study.⁵⁶ There have also been some reports of significant symptom relief on BHT compared to HRT.⁵⁵ Since there is paucity in studies that directly compare BHT to HRT, exploring the effect of BHT on women's menopausal symptoms compared to HRT is an important area of investigation in future studies. Such research would provide a better understanding of BHT's clinical benefit and role in menopause management, as well as influencing therapeutic guidelines. Inclusion of a placebo arm in such a trial might also provide valuable information on the contribution of expectancy and other psychological factors related to response to treatment.

2.5.5 Menopause and the Patient-Physician Relationship

Exploration of the participants' reflections on the relationships with their family physicians throughout their menopausal journey revealed two distinct stages: a) stage one, family physician as life line; before participants discovered BHT and b) stage two, family physician as stepping stone; after participants discovered BHT.

2.5.5.1 Stage One, Family Physician as Life Line

Participants initially turned to their family physicians with hope for help and support during their menopausal transition. Three important factors participants believed to be

missing during that initial stage: the physician's realization of the significance of menopause, preparing women for menopause, and providing women with therapeutic options. These factors were considered pivotal in maintaining a satisfactory patient-physician relationship.

2.5.5.1.1 Menopause is a Significant Time

Participants in this study reported feeling their menopause concerns were trivialized by their family physicians. They felt unheard, and related it to: not being asked questions about their menopause experience, feeling their physicians offered prescriptions early and without spending sufficient time on counselling, and not exploring their individual issues. To our knowledge, only one previous qualitative study has explored women's BHT experience and that study also reported that women were dissatisfied with their family physician interactions.⁵⁶ Women in that study described a perceived disconnect in patient-physician communication, a lack of compassion, and an overall disinterest in their needs.⁵⁶ Although there is an increasing amount of knowledge on how women experience menopause^{42, 59, 60} and multiple qualitative and quantitative studies on why women choose HRT or not,^{8, 19, 49, 51, 54, 61-63} little is known about menopausal women's expectations during contact with their family physicians. A few studies have identified some factors that contribute to women feeling supported during menopause related visits including: feeling the health care practitioner showed understanding, provided sufficient information to help them understand menopause, discussed treatment options, screened for other diseases, and put the women in charge of their decisions.^{8, 42, 64} However, those studies did not explore the factors that constitute a positive menopause related patient-physician encounter. Thus, a clearer understanding of women's experiences concerning

menopause health visits and their views on the role the family physician should take is necessary to enhancing patient- physician communication. Studies that focus on women's thoughts and expectations during menopause counselling may significantly help family physicians better structure the time they spend and the materials they provide during menopause related visits.

2.5.5.1.2 Prepare Women for Menopause

Many participants in our study felt uninformed about what to expect during menopause, a factor that contributed to their sense of confusion and chaos. They talked about how physician-initiated menopause conversations and an anticipatory approach to menopause care through education and pre-emptive preparation could have significantly reduced their anxiety about experiencing new physical and emotional symptoms, as well as help overcome communication barriers. Studies have reported that women commonly express uncertainty in their expectations about menopause,^{59, 65, 66} and lack knowledge about the spectrum of menopause changes.^{42, 59} Women's confusion and lack of menopause knowledge has been partially attributed to the presence of social barriers that prevent women from discussing menopause and obtaining support from health professionals. These barriers include: menopause being viewed as a taboo subject within society; the inability to seek support for fear of crying; and fears that discussion of menopausal symptoms might be viewed as attention-seeking.⁴² Even though a few participants in our study did talk about similar social barriers, the majority believed feelings of isolation, lack of sympathy, and embarrassment in communicating with male physicians were the main barriers interfering with their ability to seek support. This variation in findings could partially be explained by differences in research methodology and participant

background between studies, as the previously mentioned study involved focus group interviews of participants that worked in a single health care facility in Scotland.

It has been proposed that women have been taught from a young age that the physiology of their feminine bodies is private and should not be discussed.⁶⁶ Thus, a theme of lack of information extends throughout their lifespan and uninformed young girls develop into women whose knowledge, attitudes, and beliefs about menopause are shaped by insufficient information.⁶⁶ Educational programs on menopause have been shown to increase women's knowledge about this transitional time and reduce their uncertainty.⁶⁷ Women in our study also believed an anticipatory approach to menopause care through education could have significantly reduced their uncertainty and in turn anxiety about experiencing menopause symptoms. Thus, early and pre-emptive discussions on menopause with women as they near that period in their life is an important opportunity for health promotion that would aid women in having realistic expectations of menopause and help them make healthy adjustments to experienced or anticipated changes.

2.5.5.1.3 Provide Therapeutic Options

Many participants were upset at the deficiency in therapeutic options offered by family physicians. They were also hoping that they would have a more active role in the therapeutic decision making process. Repeatedly in the literature there is an emphasis on women's desire to be actively involved in all aspects of their menopause care, especially in relation to therapeutic decisions.^{8, 48, 49, 68, 69} A review of 16 qualitative studies on women's decision making about the use of hormonal and non-hormonal remedies for the menopausal transition, reported that women valued communication with their health care

providers as long as they were treated as partners in their care and were provided an environment that facilitated open dialogue and sharing of information.⁵¹ Women also wanted information about both HRT and alternatives, guidance about possible side effects, and assistance with weighing benefits and risks for both HRT and alternative therapies.^{48, 51, 70} They appreciated providers who were available to answer questions, discuss concerns, and assist with problem solving and changes in regimens.^{48, 51, 70}

Participants in our study reported similar needs and considered them to be central to their satisfaction with their menopause related patient- physician encounter.

Participants in our study and in other studies have expressed considerable dissatisfaction with the decision-making process involved in choosing menopause therapeutic options.^{8, 45, 71, 72} Perhaps this may be explained in part because physicians may not be properly informed about the needs of patients and do not incorporate patients' concerns and personal beliefs into the decision-making process. Women have identified multiple factors that are perceived to be relevant to their decision making about HRT including: spectrum of symptom response, preventative value, media reports and medical uncertainty.⁷³ Yet analysis of physician-directed clinical guidelines recommend that women be counselled on a fraction of those domains.⁷³ Although lack of medical certainty regarding HRT has been acknowledged, there are no suggestions within clinical guidelines that guide a provider to address a patient's feelings about making a choice in the setting of evolving evidence.⁷³ Without shared recognition of the limitations of available data, true informed decision-making cannot take place. Thus the focus of menopause management dialogues should be on sharing information between physician and patient rather than simply giving information. Engaging menopausal women in such a

dialogue may lead to a better understanding of their illness experience, clearer perception of their therapeutic expectations, and ultimately reaching more informed decisions. This approach supports the need for family physicians to be patient-centered⁷⁴ during menopause counselling. Recognizing and responding to each woman's individual needs is crucial to the development and maintenance of a trusting patient-physician therapeutic relationship throughout women's menopause journeys.

2.5.5.2 Stage Two, Family Physician as a Stepping Stone

In stage two, participants were focused on accessing BHT. The family physicians' role was quite limited to either facilitating or impeding their ability to access this therapeutic choice. Factors valued by participants and considered key in facilitating their access to BHT were: family physicians expressed openness to BHT, their willingness to send a referral to a BHT provider and their support of the woman's decision to use BHT. A non-judgmental openness to this treatment modality was a vital quality in maintaining a satisfying patient-physician relationship. Participants were accepting of their physicians' lack of BHT knowledge and did not consider it to be a major obstacle. Our findings are supported by a qualitative study that explored women's path to accessing BHT.⁴⁶ However, women in that study differed from our participants in that they emphasized the importance of the providers BHT knowledge over other aspects, and considered the lack of BHT knowledge to be a significant barrier to their BHT care.⁴⁶ Women in our study did mention physician BHT knowledge as a possible barrier to BHT access, but more due to its effect on the physician's comfort level with this modality and, therefore in turn their openness. This variation in findings could be related to the fact that participants in our

study were receiving their BHT care at a specialist clinic and did not rely heavily on their family physician's expertise.

Many women were upset at their family physician's lack of follow up on their BHT experience, which they interpreted as a disinterest in their general menopause care. A few studies on women's use of complementary and alternative medicine (CAM) during menopause recognize that physicians rarely ask patients about their CAM use and patients are reluctant to initiate that conversation.^{45, 48, 75} Physicians may avoid CAM discussions due to concerns about: lack of evidence, possible harmful effects, inadequate CAM knowledge and lack of statutory regulation for most CAM therapies.⁷⁶ These findings suggest the importance of physicians' openness towards BHT and willingness to be actively involved in their patients BHT care on patients' menopause related health care and the patient-physician relationship. This is an important area for future BHT research to explore, as it would be valuable to have a better understanding of family physicians' perspective on BHT, as well as patients' expectations of the family physician's role in their BHT care. This could help in the development of appropriate recommendations for approaching BHT conversations during hormone therapy counselling and shared decision making.

2.6 Study Limitations

The main limitation of this qualitative study is that the participant sample was composed of women on BHT who visited a single urban specialised BHT clinic. This sample was purposefully chosen to insure all participants had experience of the phenomenon being studied, as we were interested in gaining a deeper understanding of how the decision to use BHT was made. Given this limitation our findings do not reflect the experience or

decision-making processes of women who receive their BHT care through their family physician. Consequently our findings may have captured a more negative view of the family physician-patient interaction during the BHT decision-making process than it would have if women who received their BHT care through their family physician were included. Furthermore, the fact that all participants were actively receiving BHT at the time of the study may explain the overwhelming positive responses of participants to this therapy, probably reflecting a subgroup of women who BHT was helpful for.

2.7 Conclusion

This study has provided a more detailed understanding of menopausal women's decision to use BHT as their therapeutic modality of choice. It has also identified that women who chose to use BHT experience a wide range of symptoms that significantly affect their quality of life. Family physicians should show awareness and understanding of the impact menopause may have on different aspects of women's lives. Anticipatory menopause counselling has been identified as an important source of reassurance for women and a key factor in developing and maintaining a satisfying patient-physician therapeutic relationship. It can begin as soon as women present with menopausal changes, or as they approach menopause. The content of the counselling should include expected changes and symptoms during menopause, what life style modification women can do to manage these changes, a general discussion on risks and benefits of all available therapeutic options including; HRT, BHT and non-hormonal alternatives. Women's options should be explained in a nonjudgmental way with BHT presented as part of a number of available choices and acknowledgment that there remains much uncertainty about the safety of many of the hormonal therapeutic options. The goal of the family physician is to

empower women through increased knowledge to reach an informed decision on their preferred management. The incorporation of different members of a health care team including nurses and pharmacists into the counselling process could aid this process and create a multidisciplinary and comprehensive team approach to menopause care.

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Chapter 3

Bio-Identical Hormone Therapy: A Qualitative Study of Family Physicians' Experiences and Views

The Women's Health Initiative study (WHI) results published in 2002, indicated an increased risk for breast cancer, venous thromboembolism, cardiovascular disease and stroke from the use of combined estrogen/progestin hormone therapy.^{1,2} Since that time, there has been a significant decrease in overall hormone replacement therapy (HRT) prescriptions. It has been reported that HRT prescriptions decreased by around 38 percent in the first year after the WHI was published.^{3,4} The findings of the WHI were widely publicized in the popular press, producing immediate and major impacts on women's use of HRT.^{3,5} It has been estimated that up to 70% of women taking HRT stopped within the first year after the publication of the WHI results; 26% of these women also reported losing trust in medical recommendations in general.^{6,7} More recent publications have criticized the widely publicized release of the WHI results,^{8,9} and questioned the interpretation and generalizability of its findings.^{10,11} Even though multiple menopause societies, including The Society of Obstetricians and Gynaecologists of Canada (SOGC), have supported the use of HRT for symptomatic menopausal women,¹² much uncertainty remains among women and their health care providers about the safety of HRT.^{13,14}

Due, in part, to the controversy surrounding the WHI, some women have chosen to use "bio-identical hormonal therapy (BHT)" or "natural hormones" as an alternative to conventional hormone preparations in the belief that they are safer.¹⁵⁻¹⁷ The "bio-identical" approach generally refers to the individualized doses of hormones that are

delivered in pharmacy compounded creams, gels, pills, sublingual tablets, or suppositories. The hormones most commonly compounded are estradiol, estrone, estriol and progesterone.¹⁸⁻²⁰ Studies about the use, safety, and efficacy of bio-identical hormones are limited because of small sample sizes and comparison of non-equivalent hormone doses.^{15, 18-20}

A key area of concern is around women's perception of BHT safety over HRT, and the influence that perception has on their decision making process.^{15-17, 21} Additionally, women have reported dissatisfaction with menopause related family physician visits and have described accounts of struggling with HRT treatment uncertainty.²²⁻²⁵ Family physicians have a fundamental role in supporting women during this transitional stage, and in providing them with sufficient information on available management options so that they may make an informed decision.^{13, 25-27} Yet studies have reported a significant change in family physicians' menopause management practice patterns since the WHI, which involves a reduction in HRT recommendation, prescription and counselling.^{28, 29} This has been linked to physician discomfort with HRT safety and adverse effects.²⁹⁻³¹ It is therefore important to understand the possible influence family physicians' perceptions of hormone therapy may have on women's decision making process to use BHT. Since there were no studies found that examined family physicians' perspectives regarding BHT or their experiences caring for women on this therapeutic modality, an appropriate initial step toward understanding family physicians' roles in women's BHT decision making process is to begin by exploring those domains.

3.1 Purpose

This qualitative study set out to explore: 1) family physicians' perceptions and thoughts about BHT, and their experiences with patients on this treatment modality; 2) the impact of the patients' decision to use BHT on the patient-physician relationship.

3.2 Methodology

3.2.1 Study Design

A phenomenological approach utilizing in-depth interviews was used. This approach carefully and thoroughly captures and describes how individuals make sense of a lived experience - how they perceive it, describe it, judge it, and feel about it - to better understand the nature or essence of the experience.³² An understanding of family physicians' experiences with women using BHT is valuable for recognizing their role in caring for this group of patients, as well as to gain a deeper insight into the overall patient-physician relationship.

3.2.2 Recruitment and Sampling

Family physicians practicing in three counties in Southwest Ontario (i.e., Middlesex, Oxford, Elgin) and who provided primary care to women 40 years of age or older were recruited for the study. Potential participants were identified through the following methods: a) a random sample of 200 family physicians was drawn from a database of family physicians practicing in Southwest Ontario maintained by the Centre for Studies in Family Medicine at Western University; b) participants of the "Bio-Identical Hormone Therapy: Understanding the Women's Decision-Making Process" study (chapter 2) were asked to consider providing the name of their family physician; c) using snowball sampling,³³ family physicians who participated in this study were asked if they knew

other interested physicians; d) the medical director at a clinic that provided BHT, and the research investigators' medical colleagues were asked for recommendations of interested family physicians. Potential participants were mailed a letter describing the study and inviting them to join (Appendix IV). Physicians who responded, met the study criteria, and consented (Appendix V) were interviewed. Recruitment ended once theme saturation and maximum participant variation was achieved.³³

3.2.3 Data Collection

In-depth interviews were conducted between May to August 2012, using a semi-structured interview guide (Appendix VI), at either the family physician's office or Western University. The questions focused on the following areas: the physicians' thoughts about BHT; their experience caring for women on BHT; their general role in managing menopause; and, the impact BHT use had on that role. Probes were used as necessary and the interview guide was adapted as new information emerged from the data analysis. Interviews, which lasted approximately 30 minutes, were audio-recorded and transcribed verbatim. Field notes and reflexive journaling³⁴⁻³⁶ were recorded during and immediately following each interview. Participants received a \$10 gift card in appreciation for participating. The study was approved by Western University's Ethics Board (see Appendix VII)

3.2.4 Data Analysis

All interview transcripts and field notes were analyzed using an interpretive and iterative process that included: 1) initial familiarization with each participant's whole descriptive account; 2) organizing recurring words, phrases and significant statements from each

participant's transcript into a coding template that was grouped in a similar fashion to the interview guide categories; 3) generating themes, and using diagrams to compare themes among participants; 4) collapsing smaller subthemes within larger thematic units; 5) identifying exemplar quotes that captured the themes; and, 6) producing the report.

Data analysis occurred concurrently with data collection and continued until theme saturation was achieved (i.e., when no new themes emerged with further interviews).³³

Initially each of three researchers (LW, GR, AT*) independently read each verbatim transcript. The researchers subsequently met to compare and combine their independent analysis on a regular basis, and synthesize the data in a comprehensive description of the key themes and overarching essence of the phenomenon. Techniques used to promote trustworthiness and credibility of the data included: a) purposeful screening to ensure exposure of participants to the phenomenon; b) audio-recording interviews, verbatim transcribing, detailed field notes to maintain methodological rigor; c) team analysis and reflexive journaling to maximize researcher transparency; and, d) constant referring back to data and field notes for verification of emerging themes.

3.3 Final Sample and Demographics

Participants (n=11) ranged in age from 35 to 64 years (mean= 48). Forty- five percent were women. All participants worked in London Ontario, with the majority (n=8) being

* LW: Lemmese Alwatban , GR: Graham Reid, AT: Amanda Terry

employed in academic teaching clinics. The remainder (n=3) worked in urban non-academic settings. All participants primarily practiced general family medicine and managed women in the menopausal age group (i.e., above age 40 years). The physicians' years in practice ranged from 5 to 36 years (mean=18.45).

3.4 Findings

Four main themes emerged from the interviews: 1) physicians' impression of BHT; 2) perceptions of patients' knowledge; 3) the impact of BHT on the physician's role; and, 4) reaching a therapeutic balance. Participants expressed some concern about their patients' understanding of BHT. Family physicians needed to reinforce risk assessment and to provide education regarding hormone therapy options so that their patients could make an informed decision when choosing BHT. They demonstrated awareness of the delicate nature of the menopausal transition for women and the role they played in managing their patients' concerns, yet described challenges in reaching a balance between patients' wishes and standard practice. The following describes each of the four themes in detail.

3.4.1 Theme 1: Physicians' Impression of BHT

The majority of participants felt they had limited information about BHT. The term "bio-identical" was confusing to most physicians in the study. They considered topical pharmaceutical HRT to be bio-identical in nature as it closely resembled the body's natural circulating hormones. BHT, defined in this study as a compounded form of bio-identical hormones, was thought to be somewhat of a marketing strategy to differentiate it from the negatively publicized HRT. Participants believed that BHT was not that different from HRT, as both were still hormones:

I personally feel it's a bit of a gimmick that someone's come up with for financial reasons, to sell a product to a niche of patients exploiting their concerns. That's come a little bit out of some of the fear and anxiety around the women's health initiative and traditional hormone therapy. I don't see it really is that much different than traditional hormone therapy.

Bio-identical hormone therapy is something that probably none of us feels like we know really a lot, and yet is that really true? Because in terms of our hormone replacement therapy, we've learned with pills but then suddenly we're using manufacturers topical [HRT preparations]. So how is that different than what this thing called bio-identical is? I think that it may just be semantics. There may not necessarily be that much of a difference.

In spite of feeling hormones in BHT and HRT were not that different, family physicians consistently reported concerns about the lack of evidence supporting BHT: "from what I understand there have never been any controlled studies or any good studies to look at the validity of bio-identical hormones". Many physicians also questioned the effectiveness and standardization of how BHT was prepared:

You know when you're compounding something you don't really know what you're going to end up with. The amounts that would go into it might be different and then who knows what happens from there once it goes into your body. There are so many variables that once it goes into the compound, you really don't know how the body is going to treat it.

In spite of concerns related to the preparation of BHT, physicians did not consider BHT to be more unsafe than traditional HRT and thus considered its clinical management comparable: "I don't believe that they're any more harmful than what we prescribe. So if I had a comfort level in terms of a woman's risk category to prescribe her hormone replacement therapy, then I would be comfortable supporting her in a trial of a bio-identical."

3.4.2 Theme 2: Perceptions of Patients' Knowledge

All family physicians in this study expressed concerns with patients' perceptions of BHT's safety, and felt patients were misled by insinuations that it was more natural: "I must say a lot of them get taken in by the word 'natural' and that it's similar to your own [hormones], and hence it's not harmful. I think that's the catch word that gets people to go and seek the bio-identical hormones". Participants attributed the idea that BHT was safe to the information sources patients were referring to including word of mouth through friends and family members' positive experience with BHT and promotion by the pharmacies prescribing it. The physicians particularly believed media sources like celebrity endorsement through television shows, books and magazines were especially influential in persuading women to choose BHT, as the following quote illustrates:

I asked them [patients using BHT] about it: tell me why did you choose this versus the other? And again the same answer, they feel that it's more natural and therefore it will not be as harmful. Because everyone has heard about the WHI study, everyone knows what a bad thing HRT is and so this [BHT] to them is not synonymous with HRT. It's a lesser evil or not even an evil ... Media [has had an effect] both ways in terms of saying bad things about HRT trials and promoting bio-identical hormones.... So fear generated by media and then a sense of security with bio-identical hormones generated by the media.

Many physicians felt that the medical community might inadvertently be encouraging women to pursue alternative and non-HRT therapies for their menopausal concerns, because of a reluctance to prescribe HRT. They believed that menopause for most women had a significant negative impact on their day-to-day lives which compelled them to search for a suitable treatment. How physicians approached the topic of hormone therapy with their patients was also thought to contribute to the patients' aversion to HRT, as reflected in comments like the following:

I think people feel uncomfortable with menopause. That's perfectly fine, menopause is uncomfortable. They [patients] now have had a huge [study] to tell you what doctors were doing was bad and therefore, they're forced to say I need to do something and so they are actually pushed to bio-identical because we're saying that hormones are bad.

On the other hand, participants thought that the individualized delivery of BHT was perceived to be more appealing by patients than the traditional approaches in medicine.

Many physicians felt that women who chose to try BHT were health conscious individuals who were invested in maintaining good lifestyle habits and were highly motivated to be involved in all aspects of their health care. These identified characteristics were believed to contribute to the patient's satisfaction with the more personalised BHT approach, as exemplified in the following description:

I think [BHT] meets a need for the patient in terms ofa potentially much more personal approach, a more customized approach... We like to customize things to have them the way we want. I'm sure the patient feels much more involved in the whole process. It's probably more face-to-face time with the practitioner who's helping them out. So there's probably a very positive perception from the patient's point of view.

General doubt in conventional medicine was another patient attribute that was considered by some family physicians to be a reason for using BHT: “[patients] who probably stay with the bio-identical come hell or high water tend to be, generally speaking, a particular group of people who do not trust medical things per se but have found their symptoms so dramatic. A lot of their life is focused on sort of natural approaches and that type of thing and taking control of themselves.”

3.4.3 Theme 3: The Impact of BHT on Physicians' Roles

Family physicians recognized their important role in caring for women during the menopausal transition, but they expressed differing opinions about how to address women's concerns. Female physicians in this study felt strongly about preparing women for menopause and taking an anticipatory approach to their care by dedicating sufficient time, educating them on symptom variations, available treatment options, and possible effects on their overall wellbeing.

Unique to menopause is a tremendous amount of information giving; perhaps more complicated than say a birth control visit. Managing expectations, confirming the normality of it all, giving some idea of sort of the options in general -medication, non-medication- other life issues that are going to occur at the same time; It's part of a process it's a stage [and] a very complicated time in their life!

Conversely, male physicians viewed menopause to be no different than any other medical condition:

I think it's just one of the things we do with managing any other medical problems. [Menopause is] a medical problem, so it's a must that we [manage] this. I would discuss what menopausal symptoms are and what is going to be as they go through this change in life ... We do this sometimes in periodic health exams.

Both male and female physicians described a definite stepwise approach to menopausal care that involved identifying symptoms and their impact on women's lives, using medications when appropriate, risk assessment and ongoing monitoring, and reaching a joint decision on when to discontinue the medication. The majority of physicians felt that being on BHT impeded the women's usual flow of care:

Normally, we try to keep in contact with our patients and follow-up. Even when a specialist prescribes a new medication often it would come back to us to continue to follow the medication and continue to prescribe it. So [BHT] is really a different model, where they're getting something from somewhere else and not

really necessarily following up with us about it ... I think it's changed that ongoing follow up piece, It tends to fall off the radar a little bit because it's maybe not on their medication list, or that they feel they're dealing with somebody else, so they don't always bring it up.

Many physicians were disappointed at not having a direct role in this aspect of their patient's care "I wasn't in the driver's seat. I was in the back seat!" "I think on some level I feel that as her doctor I'm a little bit left out in the process". They described feeling that their patients did not trust them when it came to talking about hormone therapy and believed that perhaps the BHT information sources were contributing to this impression.

... There's a bit of disbelief by the patient in terms of well "he [the family physician] doesn't really know what he's talking about". I sometimes get that inkling; like they don't trust you because you've been set up to be on the bad side.

The timing of when physicians talked to patients about hormone therapy was considered crucial in influencing the patients' thoughts about BHT, "It depends who gets to them first". One family physician described her frustration at missing that opportunity as follows:

There were a couple of [women] that really did think [BHT] was great and that it really did work for them. From that standpoint it was a little bit more awkward, because they had already experienced it and really thought that it was the better way to go, without really knowing what the alternative was. So it was a bit one sided!

3.4.4 Theme 4: Reaching a Therapeutic Balance

Physicians struggled to achieve a balance between patients' wishes and standard practice:

"... how do you balance all of that? Sort of the feeling uncomfortable, not knowing this

type of modality [BHT] and patients wanting it and needing it or thinking they need it”. Physicians identified some factors that contributed to their discomfort in providing BHT care including: lack of knowledge, concern about safety, and the potential for medico-legal consequences.

3.4.4.1 Lack of Knowledge Regarding BHT

All family physicians interviewed felt the lack of BHT knowledge put them at a disadvantage in providing patient care, as demonstrated by the following participant’s response:

Lack of knowledge! Don’t you love it when the patient comes in and wants to talk about something and you can tell you’re at the deep end and you have no idea what you’re doing there.

Family physicians reported briefly looking up literature on BHT only when patients requested this treatment. Many physicians did not feel the need to invest more time in learning about this modality as they did not have a sufficient number of patients interested in it. Two female physicians who had a higher proportion of female patients in their practice felt justified in enhancing their understanding of BHT. Participants who worked in academic-teaching practices did not feel the need to purposely teach BHT to family medicine residents, but rather focused on hormone therapy education in general. They only felt the need to talk about BHT when residents interacted with patients requesting it, and would mostly approach the conversation as they would other ambiguous areas of primary care practice:

Well I think it’s the role in teaching people about any uncertainty, and I kind of explain how I talk to patients about it, and that’s what I talk to residents about,

because I'm not going to be able to teach them everything. I'm not going to tell them which bio-identicals are good or bad.

3.4.4.2 Concern about Safety

Most participants approached their concern about BHT safety by initially offering patients alternative and more familiar therapies, including HRT. Once patients rejected those options, most physicians felt they had an important role to play in providing their patients information on BHT's probable risk, and to compare those risks to conventional HRT. The goal of these conversations was not necessarily to change patients' decisions, but rather to insure that they were making an informed decision.

You just have to accept that often, especially around this particular issue where there are very strong opinions ... it's not really worth fighting their opinion. It's just providing information, helping to make sure that they can make the best decision for them, and leaving it at that, and trying not to make it a fight.

Family physician's BHT-care centered on risk reduction by screening patients for hormone risk factors as well as encouraging their maintenance of routine monitoring.

The issue of safety was of particular concern when patients were considered to have too high a risk for conventional HRT:

I think there was a misconception that BHTs were somehow not harmful. I thought that was a big problem, because there were people on them that I didn't think should be on hormone therapy at all! Because of a family history of breast cancer or something like that. But somehow they were given the impression that the bio-identical hormones were better for them, so I thought that was an issue!

Unless I have an obvious alarm that goes off - personal history of breast cancer, something that says, "No, you shouldn't be doing this." - You let people make those decisions.

3.4.4.3 Potential “Medico-Legal Consequences”

Participants were hesitant in prescribing BHT to patients as it was not part of standard practice, yet they were willing to support their patients’ BHT choice only if they felt they were also suitable candidates for HRT, as exemplified by the following physician’s response to being asked about his comfort with BHT.

I think from a medical legal perspective, if I’m thinking with that hat on, the answer’s no. It’s not a form of therapy that I’m familiar with. From a patient care perspective, I have less of an issue because in this case I’m playing more of a supportive role, a facilitator role.

Many physicians explained how their patients specifically requested BHT, and brought in information pamphlets or even prewritten examples of prescriptions. Although physicians described feeling “uncomfortable” writing out the BHT prescriptions, they agreed to it if the hormones requested and their dosages appeared reasonable and comparable to conventional HRT. Many of the physicians interviewed reported documenting the patient’s understanding of this treatment’s “off-label use” and the patient’s awareness of the possible risks associated with hormone use. Physicians were reassured if BHT was initiated by a medical specialist as they believed patients would be properly monitored:

A few patients that have been on them [BHT] were followed very closely and were prescribed these hormones by a gynaecologist, so I felt fine, comfortable with it. Whether I would choose to prescribe them, probably not! I think knowing that the person who is prescribing them was well educated and well versed in bio-identical hormones and other hormones as well. He or she knew what they were doing, so there was that safety zone.

Even though family physicians in this study prescribed BHT at a patient's request or as refills, the majority were not open to initiating this therapy or offering it as a therapeutic option.

I'd have to have a woman asking for [BHT] and remind me what we're treating. We've got to be treating something here, and have an end point. I'd likely want to talk about how long because I wouldn't think forever is the right answer. Instead of me convincing them, they have got to convince me.

Overall participants described that the process reaching "common ground" with patients was essential to maintaining the patient-physician relationship. Being open to unconventional care and willing to listen to patients were considered to be key factors in attaining a collaborative relationship,

I think overall you have to make sure that it's an open practice to be able to discuss [BHT]. If you have a very paternalistic approach ... then you're not going to get the person to talk to you.

Just being open to listen and actually really make clear your position about [BHT], because patients do often come in with their guards up about how much to inform the physician ... I think the approach we've taken is good - listening and partnering with them to achieve the goal, which is their health.

3.5 Discussion

Family physicians in this study identified several challenges in providing menopausal care to patients on BHT, four major themes emerged: 1) the physician's perspective on BHT; 2) perceptions of patient's knowledge and understanding of BHT; 3) the impact of

this treatment on the physician's role; and 4) reaching a therapeutic balance. To our knowledge, there are no previous studies examining family physicians' perceptions and thoughts about BHT, their experiences caring for patients on this treatment modality, or the impact patients' use of BHT may have on the patient-physician relationship.

3.5.1 Physician Perspective on BHT

Physicians in this study reported a lack of knowledge about BHT, but felt that the hormone constituents were no different in effect and risk from conventional HRT – “hormones are hormones”. Although there are no studies specifically examining physicians' views on BHT there are multiple papers suggesting a consensus among experts about its comparable risk to HRT.^{19, 21} These papers support our participants' views that BHT should not be considered risk-free but rather, considered as an alternative hormone treatment. The International Menopause Society (IMS) and The North American Menopause Society (NAMS) have issued statements supporting this position: “In the absence of efficacy and safety data for BHT, the generalized benefit-risk ratio data of commercially available HT [hormone therapy] products should apply equally to BHT”.^{37,}

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Physicians in this study also expressed confusion around the term “bio-identical”. They considered both the lack of BHT knowledge and the confusion around terminology to be sources of discomfort when they counselled patients on BHT use. Comparison studies about physicians' knowledge regarding other forms of complementary and alternative medicine (CAM) have repeatedly reported similar discomfort with CAM knowledge³⁹⁻⁴²; this has been linked to a low rate of discussion about CAM issues with patients.⁴²

Furthermore, conversations around BHT may have the added complexity associated with

talking about hormone therapy in menopause. Studies have identified general discomfort among physicians in counselling women on HRT.^{30, 31} Uncertainties around hormone therapy safety and the lack of decision aids have been cited as possible causes for physician discomfort.³⁰

Other studies have noted physician interest in learning more about CAM therapies.^{39, 40, 42}

In contrast, physicians in our study did not believe there was a pressing need to expand their BHT knowledge as they did not feel its use was prevalent enough. Data on the extent of BHT use in the population are scarce; one study estimates the prevalence of compounded BHT use to be about 20% among menopausal women seeking care.¹⁶ However, the prevalence of CAM use among menopausal and peri-menopausal women ranges from 50%-75% in North America and the UK,⁴³⁻⁴⁶ and one estimate suggests 95% of women would try alternative therapies before considering HRT.⁴⁷ Since most studies did not specifically exclude BHT from their reports on CAM prevalence, the extent of BHT use may be higher than predicted. There is a need to obtain better estimates of the use of BHT in the population. It is of value for primary care physicians and policy makers to have a better understanding of the degree of BHT use and interest among women, to help with allocating time, effort and resources to this area of menopause care.

3.5.2 Perceptions of Patient's Knowledge

In the literature - including review articles, physicians' opinions and research studies on patient knowledge - there appears to be much concern about patients' understanding of BHT safety, and its possible influence on their preference to use it.^{15, 17-19, 21, 48, 49} One study specifically assessed patients' perceptions of BHT,¹⁷ and multiple review articles have analyzed different BHT internet sources, pharmacy advertisements and celebrity

endorsements, and have identified the use of persuasive and misleading terminology in the description of this treatment such as: “natural”, “risk free” and “preventative”.^{15, 17-21}

Participants in our study had similar concerns, but also felt that the dissemination of the WHI study’s negative outcomes and patients’ fears of conventional therapy were instrumental in their selection of BHT. Similar results were found in a qualitative study conducted with family physicians, internists and gynaecologists in the USA.³⁰ Physicians interviewed in our study felt that the medical community may also be contributing to patients’ aversion to HRT, by emphasising HRT risk discussion during menopausal counselling. Physician discomfort with HRT due to safety uncertainty has been well documented.^{30, 31} But it remains unclear if physicians’ discomfort with HRT can influence patients’ choices. One study of women facing breast cancer prevention/treatment decisions found physicians’ anxiety from medical uncertainty was significantly associated with women’s level of satisfaction with breast health decisions.⁵⁰

If physicians’ attitudes towards medical uncertainty may influence patients’ decision outcomes, it could impact the shared decision making process. Although there is growing literature on medical uncertainty with regard to patients’ illness experiences, prognosis and communicating risks, little attention has been given to communicating uncertainty.⁵¹⁻

⁵⁵ Even though general recommendations have been made by different panels of experts, data is lacking regarding outcomes of these approaches for either physicians or patients involved in the decision making process.⁵⁵ Thus future studies especially examining the relationship between patient behaviours that may be affected by physicians’ attitudes towards uncertainty are warranted. Such studies could aid in the development of appropriate recommendations for addressing uncertainty during hormone therapy counselling.

3.5.3 BHT Impact on the Physician's Role

Although menopause is a natural process, women have described accounts of suffering prolonged symptoms and struggling with HRT treatment uncertainty.²²⁻²⁴ Family physicians have a fundamental role in supporting women during this transitional stage. Detailed and informative menopausal counselling for women, both to help them understand symptoms and to explain available management, is required.^{13, 25-27} Family physicians in our study described different approaches in addressing menopause counselling based on their gender. Female physicians felt that counselling women on menopause involved discussions on multiple aspects of care which justified allocating specific and sufficient time to their conversation. On the other hand, male physicians were comfortable incorporating menopausal counselling into a longer periodic health visit. There may be a preference among women for dedicated menopause visits with ample time for discussion and enquiry.^{13, 25} Furthermore, the complexity involved in reaching a decision on management may require a prolonged medical encounter.^{26, 27, 56} Time constraints during routine clinic visits have been cited as a barrier to optimal communication regarding menopause.²⁵ Thus, allocating longer visits for the discussion of menopause may be beneficial. With the movement toward team-based care in Canada, the involvement of nurse practitioners or clinical pharmacists in counselling patients on menopause is another option to consider.

Participants in this study expressed concern and disappointment at the impact BHT use had on patient care and believed early discussions with patients about menopause may help maintain a therapeutic relationship. Similar findings have been reported by physicians caring for cancer patients receiving CAM.^{57, 58} Physician initiation of CAM-

related discussions with patients has been thought to promote strong, trusting and healing patient-physician relationships.⁵⁷⁻⁵⁹ Incorporating discussions on BHT early within routine menopause counselling may help bridge the communication gap and maintain a strong therapeutic relationship, as well as encourage patients to approach BHT information sources with a more analytical view.

3.5.4 Reaching a Therapeutic Balance

Reaching a balance between patient's wishes and standard practice was identified as a challenge in caring for patients using BHT. Physicians associated this challenge with their lack of BHT knowledge and especially their concerns about its safety and possible medico-legal implications. Physicians focused their efforts on emphasising the importance of risk assessment and patient education, to ensure their patient's decision to use BHT was well informed. Participants felt the timing of such conversation was imperative in influencing patients' perceptions about hormone therapy and in maintaining a therapeutic relationship after initiating BHT. The delay in initiating BHT conversations until patients request this therapy may result in potential missed opportunities for physicians to influence their patients' comprehension of inherent risks and may negatively impact the shared decision making process once patients have reached a resolve about using BHT. A qualitative study of menopausal women's information sources has indicated that most women still rely heavily on their physicians as a first professional source of health advice and information.⁶⁰ Although other studies have suggested the utilization of information sources like media and personal contacts, they described those sources as being less influential than physician input.^{61, 62} However, studies on women's decision-making during menopause have identified that less than

optimal menopause counselling may result in women's dissatisfaction with the medical encounter and in turn the loss of a trusting relationship.^{13, 25, 63, 64}

What is clear from the literature is that the current approaches in menopause care are inadequate in producing a fully informed patient who is able to reach a satisfying therapeutic decision.^{13, 25, 63, 64} For that reason particular attention needs to be paid to proper menopause counselling, that incorporates discussion on different avenues of management in a nonjudgmental compassionate manner. This approach supports the family physician's need to be patient-centered⁶⁵ during menopause counselling.

Understanding menopausal women's illness experience and responding to their individual management needs is crucial in empowering women to reach an informed therapeutic decision while maintaining a strong trusting patient-physician relationship.

3.6 Study Limitations

The main limitation of this study was that the participant sample was from urban or academic settings in one city located in Southwest Ontario. As such, views obtained may differ from family physicians working in non-academic settings or in smaller rural communities that might not have the same level of exposure to BHT. However, the physicians in this study were purposely chosen to ensure all participants had experience caring for patients on BHT.

3.7 Conclusion

Communicating about menopause raises difficult issues for both patients and physicians around symptom diversity, therapeutic uncertainty and fear of treatment risks, hence the importance of proper counselling. It is imperative for physicians to appreciate the complex nature of the therapeutic decision making process and approach it with compassion and understanding. Additionally, the role of the physician is not to decide for a patient whether to accept or decline the various forms of hormone therapy but to provide sufficient information so they may make an informed decision. Involving different members of a health care team as well as communicating with the patient's BHT practitioner may significantly enhance the counselling process, resulting in a better comprehensive team approach to menopause care.

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Chapter 4

General Discussion and Integration of Findings

Despite considerable controversy concerning the safety and efficacy of BHT,¹⁻⁴ and the lack of endorsement by the majority of menopause societies,^{5, 6} there are some women who have chosen to use BHT to manage menopause. A prominent concern about BHT use is around the possible influence misleading terms like “bio-identical” and “natural” may have on women’s perceptions of BHT safety and in turn, their decision to use them.^{4, 7-9} Descriptions of women’s use and path to accessing BHT exist in the literature.^{10, 11} However, to date there have been no studies directly exploring women’s decision-making process in choosing this therapeutic modality, or the possible influence family physicians may have on this process. This thesis sought to explore this phenomenon from the perspectives of both women who use BHT and the family physicians who care for them.

To capture the phenomenon under study, two complementary and sequential qualitative studies were conducted. The studies involved in-depth interviews with women using BHT and family physicians that care for this population. Below, findings from each study are compared and contrasted and over-arching themes are highlighted. General recommendations and possible policy implications related to the decision-making process of using BHT are then presented.

4.1 Integrated Summary of Findings

There was strong congruence between the findings from the interviews with women and family physicians. Common themes include: 1) the complexity of menopause counselling,

2) the dichotomy between women's and physicians' views of BHT, and 3) the patient-physician relationship.

4.1.1 Theme 1: The Complexity of Menopause Counselling

There was synergy in participants' accounts of the impact menopause had on women's quality of life. Participants in both studies recognized the significance of this transitional period and the importance of the family physician's role in reassuring and normalizing women's menopause experiences. Furthermore, participants unanimously expressed how they believed a pre-emptive approach to menopause counselling was vital in relieving women's fears and confusion about menopause symptoms. Women participants emphasized the importance of having sufficient time during menopause-related visits with their family physician to fully explore their concerns and discuss therapeutic options. However, only female physicians felt menopause counselling was complex and required longer and dedicated health visits to ensure women felt supported; male physicians did not express these ideas. This in part could be explained by female physicians general tendency to provide more female preventative care,^{12, 13} spend more time with patients, engage patients in discussions of social and psychological contexts and facilitate patient participation and partnership more effectively than male physicians.^{12, 14-16} The gender difference in approaching menopause counselling could result in women feeling a lack of empathy from male physicians. Many women participants in our study did talk about the physician's gender as a possible obstacle in their menopause health care, yet most women participants felt it was something that could easily be overcome. Women suggested that male physicians should initiate the conversation on menopause; show knowledge related to women's health; spend sufficient time during visits; and demonstrate a caring attitude.

Studies have identified that patient-centeredness; sufficient visit duration; and the demonstration of compassion can eliminate patient perceived gender bias.^{15, 17-19} Also, there appears to be a preference among women for dedicated menopause visits with ample time for discussion and enquiry.^{20, 21} Furthermore, the complexity involved in reaching a decision on menopause management may require a prolonged medical encounter.²²⁻²⁴ Both of our studies support the value of dedicated menopause visits that provide patients with adequate time to explore their concerns and discuss management options. This is a critical finding, since primary care clinic time constraints may be a factor interfering with the physician's ability to provide satisfactory counselling durations. This could result in women's dissatisfaction and loss of trust in conventional medical care.^{20, 21, 25, 26} A few studies have identified nurse practitioners and pharmacists to be important resources for women going through menopause.^{21, 27} Thus, the incorporation of a team approach in menopause care that would involve both nurse practitioners and clinical pharmacists could aid in providing patients with the necessary counselling duration, as well as providing support in reaching a decision on menopause management. Other approaches to consider would be the use of educational material like pamphlets, websites or public lectures that would serve as an initial foundation for more focused menopause counselling during clinic visits. The latter approach also provides women with additional knowledge, which has been shown to reduce uncertainty and anxiety during menopause.²⁸

4.1.2 Theme 2: The Dichotomy between Women's and Physicians' Views of BHT

Participants from both studies strongly endorsed the concept that women's resolution to use BHT was a critical junction in their menopause care. It was identified as a turning

point in women's views of their family physician's role during menopause. The family physician's scope of menopause care was significantly reduced to either providing a BHT prescription, or a referral to a BHT provider. Family physician participants also reported that menopause counselling was no longer effective after women had reached a resolution to use BHT. Data from both studies identified women's fear of HRT and belief that BHT was a safer alternative to be a strong factor in influencing their decision to use BHT. This was further supported by the women's significant symptom resolution on BHT. The dichotomy arose between women's beliefs of BHT safety and family physicians' concerns about the unsupported nature of those beliefs. This dichotomy is also evident in the literature as studies of women using BHT have identified similar beliefs that BHT is less harmful than HRT,^{7, 8, 10} while physicians have voiced concerns about those beliefs,^{1, 3, 4, 8, 9, 29, 30} and the majority of menopause societies have not endorsed BHT use^{5, 6}

Physicians' reluctance to support this treatment modality was considered by women participants in our study to be a barrier to BHT access, and in turn the physicians' perceived closed attitude was a source of dissatisfaction with care. Similarly studies on other forms of alternative medicine have identified the openness of the health care provider to the patients chosen modality of care to be a key factor in promoting collaborative care.³¹⁻³³ Although both women and physician participants in our studies did recognize that the physician's openness to BHT was imperative to maintaining a therapeutic relationship thereafter, it is unclear what constitutes an open attitude, or what factors are fundamental in conveying openness to BHT. Future research which would explicitly explore women's expectations during BHT requests or even other forms of alternative therapy requests would be valuable in helping to bridge communication barriers and lessen misinterpretations.

4.1.3 Theme 3: The Patient-Physician Relationship

Patient-physician communication is perhaps the most significant component of the medical encounter, is a bridge to finding common ground, and the cornerstone of a solid therapeutic relationship.³³⁻³⁵ Participants from both studies identified “listening” to be the most impotent factor in establishing a satisfying menopause related patient-physician encounter.

As a [family physician] community we could improve the [menopause counselling] process by being more upfront about our willingness to listen ... because we don't make that explicit, and I think a lot of patients have the perception that it's them versus us.

Women participants especially reported feeling heard by their family physicians if they demonstrated interest in their menopause experience and the impact it had on their quality of life. Unfortunately, many women were unsatisfied with their initial menopause related health visit as they felt rushed into taking a prescription to manage their symptoms, which suggested a lack of the family physicians' interest in their menopausal experiences.

Although family physician participants in our study reported approaching menopause care in a step- wise manner that involved symptom exploration, menopause education, reassurance, and management counselling, women participants did not perceive that approach. This variation in findings could be related to the fact that none of the physician participants in our study were involved in the actual care of the women participants. As a result, participant specific patient-physician dynamics would not be captured. However, studies that have reported on women's positive menopause-related physician encounters identified a similar approach to menopause care.³⁶ These findings signify the importance of the physician adequately exploring women's menopause experiences and the effect it may have on women's satisfaction with the overall patient-physician encounter.

A prominent finding between the two studies was the exclusion of the family physician from women's menopause care as a consequence of BHT use. Participants from both studies demonstrated disappointment at this loss and sought a more shared approach to care. Women participants interpreted family physicians lack of interest in their BHT use as disinterest in their overall menopause care. Similar communication gaps have been identified between physicians and cancer patients who use complementary and alternative medicine (CAM).^{31, 37} However, the patient-physician relationship was enhanced when the topic of CAM was discussed.³⁸ Physician initiation of CAM-related discussions has also been thought to promote strong, trusting and healing patient-physician relationships.³¹⁻³³ Thus, the importance of family physicians' listening skills and their expressed interest in women's menopause experiences appears to be particularly important in the context of BHT. This aspect of women's care would significantly benefit from family physician initiated conversations and continued follow up to ensure the preservation of the patient-physician relationship.

4.2 Thesis Limitations

The findings of this thesis are not intended to be generalized to all family physicians, nor to all women seeking menopause care. Although physician participants possessed common practice profiles in urban or academic locations, they did reflect diversity with respect to their gender, age and years in practice. Despite this limitation, all physician participants in our study did care for women on BHT in their practice and thus their views do reflect family physicians actual experiences with BHT care regardless of their practice location.

Patient participants reflected a balance in age, menopausal status, years since last period, prior HRT and duration of BHT use; they were all recruited from an urban, specialized BHT practice. Since participants received their BHT care at a specialist clinic and did not rely on their family physicians for that aspect of their care, this may have contributed to the exclusion of their family physicians from their overall menopause care. In addition, the perspectives of patients who might be receiving BHT through their own family physician could not be captured. However, a more in-depth understanding of family physicians' and women's experiences with BHT, specifically what influences the decision-making process was achieved.

4.3 Conclusion

The collective findings of both studies demonstrate the complexity of menopause care. The findings offer important information about the role of the family physician and the patient-physician relationship in the journey of women choosing to use BHT to manage menopause symptoms; in particular the value placed on family physicians spending adequate time exploring women's experiences, listening to their concerns and being open to the independence of their therapeutic choices. This thesis also demonstrates that women seeking menopause care regard the primary care practice as a place of support, reassurance and education, and are hoping for a more shared approach in their menopause care; especially with regard to the implementation or organization of varying treatment options.

The integration of a team approach in menopause care is a strategy that could support the process of comprehensive menopause management. Since counselling is particularly

important, different team members could be more closely integrated into patient support and education. The value of a team based approach resides in its ability to achieve and maintain satisfactory menopause care within the primary care setting and in reducing health care fragmentation.³⁹ In order to make this a reality; action on the part of policy makers and medical organizations is required to increase facilities and funding available for collaborative team based menopause care.

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Appendices

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(Appendix I) Letter of Invitation for Women's Study

Southern Ontario Fertility
Technologies (S.O.F.T.)
XXXXXXXXXXXXXXXXXXXX
Tel: xxx-xxx-xxxx



Date: April 9, 2012

Dear <<Patient's Name>>,

Researchers from Western University are doing a study exploring menopausal women's thoughts and experiences receiving Bio-identical hormone therapy (BHT). This is being studied so that family physicians might have a better understanding of menopausal women's choice to use BHT and in turn will be able to provide them better care.

You are being invited to participate in an interview as part of the study, entitled '**Bio-Identical Hormone Therapy: Women's Decision-Making Process and Family Physicians' Views**' as you have been identified through our records to be a women experiencing menopause who has received Bio-identical Hormone Therapy (BHT). The interview will take approximately 45-60 minutes, and take place at a location and time that is convenient for you. If you prefer, a telephone interview could be arranged. You will be asked to respond to a series of questions about: your menopausal experience, your thoughts on BHT and experience using it. The researchers are looking for women of the age of 40 or older who are on BHT.

Your decision to participate or not will not affect the services you receive at the Southern Ontario Fertility Technologies (S.O.F.T.)

If you are interested in participating or have questions about the study please contact Dr. Lemmese Al-watban at (xxx) xxx-xxxx or email her at xxxxxxxx@xxxxxx or Dr. Graham Reid at (xxx) xxx-xxx x.

Thank you for considering participating in this study

<<Signature of SOFT clinic professional>>

(Appendix II) Interview Guideline for Women's Study

INTERVIEW GUIDELINE: WOMEN PARTICIPANTS

Introduction to interview:

This study is about exploring menopausal women's thoughts and experiences about receiving Bio-identical hormone therapy (BHT). In this interview, I will be asking you questions in five main areas relating to your menopausal history, your menopause treatment history, your decision to use BHT, your experience using it and your family doctor's role in managing your symptoms. At the end of the interview I will ask a few demographic questions. The aim of the interview is to better understand your experience as a women going through menopause and your choice to use BHT.

A) Menopausal history and symptom severity:

To begin, I would like you to tell me about what the transition to menopause was like for you.

Probe for the following if they do not emerge:

- In what ways has menopause affected you physically?
- In what ways has menopause affected you emotionally?
- In what way did menopause impact your life? (Work, social or interpersonal relationships)

B) Treatment history before bio-identical hormones:

Now, that you have told me about your experience of menopause. I am interested in what you did to help relieve the symptoms of menopause before you tried Bio-identical hormones (BHT)?

Probe for the following if they do not emerge:

- Tell me about your experience with any medications or herbal supplements that you took before BHT to help with your symptoms?

C) Decision to use BHT:

1) Since you have shared with me your experience with other menopausal treatments, I would like you to tell me about what made you decide to use BHT?

Probe for the following if they do not emerge:

-Did anyone influence your decision (friends, family, members of health care and alternative practitioners)? How?

-What attracted you to this treatment or what made it appealing?

- What were some of the concerns you had about BHT? How did that influence your decision to use it? Do you still have those concerns?

2) Where did you learn or hear about BHT? (Information sources)

Probe for the following if they do not emerge:

-Do you feel you have a good understanding of this treatment (effects and risks)

- In your opinion how is BHT different from conventional HT that your family doctor or gynecologist might prescribe?

D) Personal experience on BHT:

Now that you have shared your reasons for choosing BHT, could you tell me about your experience using it?

Probe for the following if they do not emerge:

- How long have you been on BHT?

- How was your initial response when starting BHT?

- How is your response to BHT now?

-What do you like most about the BHT treatment approach? Why?

- What do you like least about the BHT treatment approach? Why?

E) Interaction with family doctor:

1) What do you feel is the role of a family doctor with regard to a women's menopausal health?

2) Do you feel you can talk to your family doctor about your BHT use?

Probe for the following if they do not emerge:

-Do you feel being on BHT has changed your interaction with him/her in some way?
How?

3) What issues do you think could prevent women from discussing BHT use with their family doctor?

4) What issues do you think could prevent doctors from discussing BHT use with their patients?

5) How do you think the situation may be improved?

Demographic information:

As we are approaching the end of this interview I would like to ask you a few demographic questions

1) How old are you?

2) Are you pre or post menopausal (i.e. have you not had a period for 1 year)

If post-menopausal.

What is your best estimate of when menopause started for you?

____ Months &/or ____ Years ago.

3) Was your menopause natural or due to a hysterectomy?

4) People living in Canada come from many different cultural and racial backgrounds. How would you best describe your race or color?

INTERVIEWER: *Do not read categories to respondent- Mark all that apply*

- | | |
|--|---|
| <input type="checkbox"/> White | <input type="checkbox"/> Arab |
| <input type="checkbox"/> Chinese | <input type="checkbox"/> West Asian (e.g. Afghani, Iranian) |
| <input type="checkbox"/> South Asian (e.g. East Indian, Pakistani, Sri Lankan) | <input type="checkbox"/> Japanese |
| <input type="checkbox"/> Black | <input type="checkbox"/> Korean |
| <input type="checkbox"/> Filipino | <input type="checkbox"/> Aboriginal (North American Indian, Metis or Inuit) |
| <input type="checkbox"/> Latin American | <input type="checkbox"/> other (specify): _____ |
| <input type="checkbox"/> Southeast Asian (e.g. Cambodian, Indonesian, Laotian, Vietnamese) | |

5) What is the highest level of education that you have attained?

INTERVIEWER: *Do not read categories to respondent*

- | | |
|---------------------------------------|--|
| <input type="checkbox"/> no schooling | <input type="checkbox"/> high school graduate |
| <input type="checkbox"/> 1-5 years | <input type="checkbox"/> some trade, technical or vocational school |
| <input type="checkbox"/> 6 years | <input type="checkbox"/> some community or business college |
| <input type="checkbox"/> 7 years | <input type="checkbox"/> diploma/certificate from community college, CFGEP, nursing school or university |
| <input type="checkbox"/> 8 years | <input type="checkbox"/> bachelor/undergraduate degree (BA, BSc, BEd, BSW, etc.) |
| <input type="checkbox"/> 9 years | <input type="checkbox"/> masters degree (MA, MSc, MEd, MSW, etc.) |
| <input type="checkbox"/> 10 years | <input type="checkbox"/> professional degree (medicine, dentistry, veterinary medicine, optometry, law) |
| <input type="checkbox"/> 11 years | <input type="checkbox"/> earned doctorate (PhD, DSc, DEd, etc.) |
| <input type="checkbox"/> 12 years | <input type="checkbox"/> other (specify): _____ |
| <input type="checkbox"/> 13 years | |

6) What is your current marital status? Are you married, living with a partner, or common law, widowed, divorced, separated, or have you never been married?

INTERVIEWER: *Do not read categories to respondent (Check one response)*

- 1 married
- 2 living with a partner/common law
- 3 widowed

- 4 divorced
- 5 separated
- 6 never been married

7) To help us describe the group of women that we've interviewed for this study, we would like to know the best estimate of your household income from all sources in the past 12 months. Which of the following is the best estimate of your household income from all sources in the past 12 months

INTERVIEWER: *Read categories to respondent*

- ☐ less than \$5,000
- ☐ \$5,000 - \$9,999
- ☐ \$10,000 - \$19,999
- ☐ \$20,000 - \$29,999
- ☐ \$30,000 - \$39,999
- ☐ \$40,000 - \$59,999
- ☐ \$60,000 - \$79,999
- ☐ \$80,000 - \$99,999
- ☐ \$100,000 – \$119,999
- ☐ \$120,000 or more
- ☐ I Choose Not to Answer

Thank you for participating in this study



(Appendix III) Letter of Information and Consent for Women's Study

Bio-Identical Hormone Therapy: Women's Decision-Making Process and Family Physicians' Views

LETTER OF INFORMATION FOR WOMEN

Investigators:

Graham J. Reid, Ph.D., C.Psych.	Psychology & Family Medicine, Western University	Principal Investigator
Amanda Terry, Ph.D.	Family Medicine, Western University	Co-Investigator
John Jordan, MD,CCFP, MCISc, FCFP	Family Medicine, Western University	Co-Investigator
Lemmese Al-watban MD,CCFP	Family Medicine, Western University	Co-Investigator

Purpose: The purpose of this research project is to learn about menopausal women's thoughts, feelings, attitudes and behaviours relating to their decision to use Bio-identical Hormone therapy (BHT). The "bio-identical" approach refers to individualized doses of hormones that are custom-made and compounded by a pharmacy in the form of creams, gels, pills, or suppositories for an individual according to a healthcare provider's prescription. This is being studied so that physicians may have a better understanding of menopausal women's choice to use BHT, and in turn may be able to provide them better care. You are being invited to participate in this research project because you are a woman experiencing menopause, who has received BHT.

Procedures: If you agree to participate in this study, you will be interviewed about your menopausal experience, your thoughts on BHT and experience using it.

This interview will take approximately 45-60 minutes, and take place at a location and time that is convenient for you. If you prefer, a telephone interview can be arranged. The interview will be audio -recorded.

A separate part of this project involves interviewing family physicians. You will be asked if you would be willing to provide us the name of your family physician. If so, we would contact your family physician and invite him/her to be participant as well. However, your identity would not be revealed to your family physician nor would the fact that you are participating in this study.

Participant's Initials: _____



Reimbursement

In appreciation for your time you will receive a (\$10 Tim Horton's or alternative) gift card.

Risks and Benefits

There are no known risks to your participation in this study. There are no known benefits to you personally associated with your participation in this research. The benefits of participating in the study include helping family physicians better understand why women chose to use BHT and what the experiences and decision-making of women related to BHT. It is hoped that this information can assist family physicians to provide better care to women as they experience menopause.

Voluntary Participation:

Participation in this study is voluntary. You may decline to participate, decline to answer any questions or withdraw from the study at any time. Your current and future care at the Southern Ontario Fertility Technologies (S.O.F.T.) clinic will not be affected in any way if you chose not to participate or withdraw from the study.

Confidentiality and Privacy:

All information obtained for the study is confidential. The content of the audio-recorded interviews will be transcribed with any identifying information removed. All participants will be given a study identification number (ID) and their interview data will be identified only by their ID number. Identifying information such as your name will be kept separate from your interview. All paper forms will be kept in a locked file cabinet at the offices of the researchers. All electronic files will be stored on the researchers' computers with encrypted protection. Information in this study is only for research. Although we recruited you from the Southern Ontario Fertility Technologies (S.O.F.T) clinic, the research team is based at the Western University in the Department of Family Medicine. Information gathered for this study will not be shared with the staff at the SOFT clinic. If you choose to identify your family physician, she/he would not be told about your participation in this study.

Participant's Initials: _____



When the study results are presented or published your name or other identifying information will not be used. At the end of the study, all paper documents will be scanned into an electronic file and the originals shredded. All the electronic data will be maintained for a period of 5 years after the last publication and then destroyed. This study is part of a Master's thesis for Lemmese Al-watban, MD at Western University Ontario.

Representatives of Western University's Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

Waiver of Rights:

You do not waive any legal rights by signing the consent form.

Contact Information:

This letter is for you to keep. If you have any questions about the conduct of this study or your rights as a participant in this research, you may contact: The Office of Research Ethics at (xxx) xxx-xxx or by email at xxxxxxx@xxxxxx.

If you have questions about the study itself, please contact Dr. Lemmese Alwatban at (xxx) xxx-xxxx or email: xxxxxxxxx@xxxxxx or Dr. Graham Reid at (xxx) xxx-xxxx.

Sincerely,

Lemmese Al-watban, MD, CCFP

*Master of Clinical Science in Family
Medicine (MCIsc) student*

Dr. Graham Reid, C. Psych.

*Associate Professor, Psychology, Family Medicine &
Paediatrics*

Participant's Initials: _____



PARTICIPANT CONSENT FORM

Bio-Identical Hormone Therapy: Women's Decision-Making Process and Family Physicians' Views

I have read the Letter of Information, have had the nature of the study explained to me, and I agree to participate. All questions have been answered to my satisfaction.

Signature

Date

Printed Name

Witness:

Signature

Date

Printed Name

☐ **Verbal agreement prior to telephone interview**

Signature: _____ Date: _____



(Appendix IV)Letter of Invitation for Family Physician Study

Dear <<Physician's Name>>,

Researchers from The Centre for Studies in Family Medicine at Western University are interviewing family physicians in Southwest Ontario who provide primary care to menopausal women. They are interested in exploring family physicians' perceptions and thoughts about Bio-identical Hormone Therapy (BHT) and their experiences with patients on this treatment modality. The results will help them better understand why women chose to use BHT, and how that choice might impact the patient-doctor relationship.

The study, entitled '**Bio-Identical Hormone Therapy: Women's Decision-Making Process and Family Physicians' Views**' involves an interview that will take approximately 30 minutes, and take place at a location and time that is convenient for you; a telephone interview may be arranged if you prefer. You will be asked to respond to a series of questions about: Your thoughts on BHT, the role a family doctor plays in managing menopausal women's symptoms and your experience in caring for women on BHT.

Participation in this study is voluntary. You may decline to participate, decline to answer any questions or withdraw from the study at any time.

Dr. Al-watban will contact you by telephone within the next week to answer any questions and schedule an interview if you are interested in participating.

Alternatively, you are welcome to contact Dr. Lemmese Al-watban at (xxx) xxx-xxxx or email her at xxxxxx@xxxxx or Dr. Graham Reid at (xxx) xxx-xxxx, to discuss the study.

Thank you for considering participating in this study

Sincerely,

Lemmese Al-watban, MD, CCFP
*Master of Clinical Science in Family Medicine
(MCISc) student*

Dr. Graham Reid, C. Psych.
*Associate Professor, Psychology, Family
Medicine & Paediatrics*



(Appendix V) Letter of Information and Consent for Family Physician Study

Bio-Identical Hormone Therapy: Women's Decision-Making Process and Family Physicians' Views

LETTER OF INFORMATION FOR FAMILY PHYSICIANS

Investigators:

Graham J. Reid, Ph.D.C.Psych.	Psychology & Family Medicine, Western University	Principal Investigator
Amanda Terry, Ph.D.	Family Medicine, Western University	Co-Investigator
John Jordan, MD,CCFP, MCISc, FCFP	Family Medicine, Western University	Co-Investigator
Lemmese Al-watban MD,CCFP	Family Medicine, Western University	Co-Investigator

Purpose: The purpose of the research project is to explore Southwest Ontario practicing family physicians' perceptions and attitudes with regard to Bio-identical Hormone Therapy (BHT), and their experiences with patients on this treatment modality. The "bio-identical" approach refers to individualized doses of hormones that are custom-made and compounded by a pharmacy in the form of creams, gels, pills, or suppositories for an individual according to a healthcare provider's prescription. We seek to better understand why women chose to use BHT and how that choice might impact the patient-physician relationship.

You are being invited to participate in this research project for one of the following reasons:

- 1) A patient who participated in an interview is part of the study identified you as her family physician.
- 2) Another family physician who participated in this study suggested we contact you.
- 3) You are a family physician practicing in southwestern Ontario.

Procedures: If you agree to participate in this study, you will be interviewed about your thoughts on BHT, the role a family physician plays in managing menopausal women's symptoms and your experience in caring for women on BHT. This interview will take approximately 30 minutes, and take place at a location and time of your choice. If you prefer, a telephone interview can be arranged. The interview will be audio-recorded.

Participant's Initials: _____



Reimbursement

In appreciation for your time you will receive a (\$10 Tim Horton's or alternative) gift card.

Risks and Benefits

There are no known risks to your participation in this study. There are no known benefits to you personally associated with your participation in this research. The information gathered in this study will provide family physicians a better understanding about why women chose to use Bio-identical hormones and how that choice might impact the patient-physician relationship. It is hoped that information can assist family physicians to provide better care to women as they experience menopause.

Voluntary Participation:

Participation in this study is voluntary. You may decline to participate, decline to answer any questions or withdraw from the study at any time.

Confidentiality and Privacy:

All information obtained for the study is confidential. The content of the audio-recorded interviews will be transcribed with any identifying information removed. All participants will be given a study identification number (ID) and their interview data will be identified only by their ID number. Identifying information such as your name will be kept separate from your interview. All paper forms will be kept in a locked file cabinet at the offices of the researchers. All electronic files will be stored on the researchers' computers with encrypted protection. Information in this study is only for research. When the study results are presented or published, your name or any other identifying information will not be used. At the end of the study, all paper documents will be scanned into an electronic file and the originals shredded. All the electronic data will be maintained for a period of 5 years after the last publication and then destroyed.

This study is part of a Master's thesis for Lemmese Al-watban, MD at Western University.

Representatives of Western University's Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

Participant's Initials: _____



Waiver of Rights:

You do not waive any legal rights by signing the consent form.

Contact Information:

This letter is for you to keep. If you have any questions about the conduct of this study or your rights as a participant in this research, you may contact: The Office of Research Ethics at (xxx) xxx-xxxxx or by email at xxxxxxx@xxxxxxx.

If you have questions about the study itself, please contact Dr Lemmese Alwatban at (xxx) xxx-xxxx or email: xxxxxxx@xxxxxxx or Dr. Graham Reid at (xxx) xxx-xxxx.

Sincerely,

Lemmese Al-watban, MD, CCFP

*Master of Clinical Science in Family Medicine
(MCISc) student*

Dr. Graham Reid, C. Psych.

*Associate Professor, Psychology, Family
Medicine & Paediatrics*

Participant's Initials: _____



PARTICIPANT CONSENT FORM

Bio-Identical Hormone Therapy: Women's Decision-Making Process and Family Physicians' Views

I have read the Letter of Information, have had the nature of the study explained to me, and I agree to participate. All questions have been answered to my satisfaction

Signature

Date

Printed Name

Witness:

Signature

Date

Printed Name

☐ **Verbal agreement prior to telephone interview**

Signature: _____ Date: _____

(Appendix VI) Interview Guideline for Family Physician Study

INTERVIEW GUIDELINE: FAMILY PHYSICIANS

Introduction to Interview:

This study is about exploring family physicians' perceptions and thoughts about Bio-identical Hormone therapy (BHT) and their experiences with patients on this treatment modality. I will be asking you questions in four main areas relating to your thoughts about BHT, your experience caring for women on BHT, the family doctor's role and reasons why women chose BHT. At the end of the interview I will ask a few demographic questions. The aim of the interview is to better understand your thoughts regarding BHT and your approach to caring for menopausal women.

1) I would like to start by asking you to share your thoughts about Bio-identical hormone therapy?

Probe for the following if they do not emerge:

- How is it different from conventional hormone therapy?
- What do you think about the validity of this treatment modality?

2) Have you had women in your practice on BHT? What is your experience in caring for them?

Probe if the following if they do not emerge:

- Have you experienced some challenges in their care? What are they?
- Have you been able to overcome them? How? If not why do you think that is?
- Have you questioned their choice of BHT? (understanding of the reason to use it vs. trying to discourage them from using it)

3) Could you tell me about what you think the role of a family doctor is in managing women's menopausal symptoms in general?

Probe for the following if they do not emerge:

- Has women's decision to use BHT changed that role? How? Why?

- Does the patient-doctor relationship change? How? Why?

4) In your opinion what factors influence a woman's decision to use BHT?

Probe for the following if they do not emerge:

- Do you feel you have a role in their decision making process? How?
- What issues do you think could prevent women from discussing BHT use with their family doctor?
- What issues do you think could prevent doctors from discussing BHT use with their patients?
- How do you think the situation may be improved?

Demographic information:

-How old are you?

-How many years have you been in practice?

- How would you categorize your practice (Urban vs. Rural)?

*Gender filled in by interviewer (male /female)

Thank you for participating in this study

(Appendix VII) Ethics Approval

re-issued



Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Graham Reid
File Number: 102451
Review Level: Delegated
Approved Local Adult Participants: 40
Approved Local Minor Participants: 0
Protocol Title: Bio-Identical Hormone Therapy: Women's Decision-Making Process and Family Physicians Views 18962E
Department & Institution: Schulich School of Medicine and Dentistry/Family Medicine, Western University
Sponsor:
Ethics Approval Date: May 01, 2012 Expiry Date: December 31, 2012
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Western University Protocol		
Other	Appendix I women invitation letter from SOFT	
Letter of Information & Consent	Appendix III Letter of information and consent for Women	2012/04/23
Other	Appendix IV letter of invitation Family Physician	
Other	Appendix V Family Physician Telephone Follow UP	
Letter of Information & Consent	Appendix VII letter of information and consent for family physicians	2012/04/23

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Signature _____

Ethics Officer to Contact for Further Information

This is an official document. Please retain the original in your files.

The University of Western Ontario
Office of Research Ethics

Curriculum Vitae

Lemmese Farouk Al-Watban, MBBS, CCFP

Education

- 2009- Present Master of Clinical Science in Academic Family Medicine Candidate**
University of Western Ontario
London, Ontario, Canada
- 2012- Present Sexual Health Fellow**
McMaster University
Hamilton, Ontario, Canada
- 2011-2012 Forth Year Residency training in Family Medicine Enhanced**
skills: Women's Health
University of Western Ontario
London, Ontario, Canada
- 2010-2011 Third year Residency training in Family Medicine Enhanced**
skills: Academic Family Medicine
At the University of Western Ontario
London, Ontario, Canada
- 2007-2009 Family Medicine Residency training, Certificate of the College of**
Family Physicians of Canada (CCFP) Degree
University of Alberta
Edmonton, Alberta, Canada
- 2008 Licentiate of the Medical Council of Canada**
- 2004-2005 Internal Medicine Residency training**
King Faisal Specialist Hospital & Research Centre
Riyadh, Saudi Arabia
- 2003-2004 Medical Internship training**
King Khalid University Hospital and King Fahad National Guard
Hospital
Riyadh, Saudi Arabia
- 1997-2003 Bachelor of Medicine and Surgery (MBBS) with Honors**
King Saud University (College Of Medicine) ,
Riyadh ,Saudi Arabia

Awards and Academic Distinctions

- 2009** **College of Family Physicians of Canada (CFPC) Family Medicine Resident Award for Scholarship**
- The award recognizes the outstanding academic accomplishments of family medicine residents
- 2006 -2013** **King Saud University Academic Scholarship**
King Saud University
Riyadh, Saudi Arabia
- 2007-2013** **King Abdullah Scholarship**
Government of Saudi Arabia
- 1997-2003** **King Saud University, College of Medicine Honours List**
Riyadh , Saudi Arabia

Professional Experience

- 2012-2013** **Sexual Health Unit**
Juravinski Hospital
Hamilton ,ON
- 2012-2013** **Pelvic Pain Clinic**
Juravinski Hospital
Hamilton ,ON
- 2011-2012** **Post Traumatic Stress Disorder Clinic and Research Unit (PTSD)**
University of Western Ontario, London Health Sciences Centre
London ,ON
- 2011-2012** **First Episode Mood and Anxiety Program (FEMAP)**
London Health Sciences Centre, Adult Mental Health Services
London ,ON
- 2011-2012** **Eating Disorders Program**
London Health Sciences Centre, Child and Adolescent Mental Health
Care Program.
London, ON
- 2011-2012** **Regional Sexual Assault and Domestic Violence Treatment Centre**
St. Joseph's Health Care London
London, ON

2011	Menopause Clinic Grey Nuns Community Hospital Edmonton, AB
2011	Osteoporosis Clinic Grey Nuns Community Hospital Edmonton, AB
2011	True Balance Institute: Health and Beauty Clinics/ Bio-identical Hormone therapy Sherwood Park, AB
2010-2011	St. Joseph's Family Medical and Dental Centre London, On
2009-2010	Meadowbrook Medical Clinic Edmonton, AB
2007-2009	Meadowlark Family Clinic and Health Centre Edmonton, AB
2005-2006	Family Medicine Clinics King Khalid University Hospital Riyadh, Saudi Arabia

Academic and Teaching Experience

2012-2013	Supervising and Teaching Gynecology/ Obstetric Residents Sexual Health Care unit Hamilton, ON
2012-2013	Review of manuscripts for the Journal of Clinical Rheumatology
2013	Presentation, Scleroderma Society of Ontario “Scleroderma and Sexuality” Mississauga, ON
2013	SOO Examiner for the Collage of Family Physicians of Canada

- 2010-2011** **Development and Delivery of Family Medicine Resident group sessions:**
 “Mood disorders” “ Antidepressant Therapy” and “Women's Sexual Health”
 St. Joseph's Family Medical and Dental Centre
 London, On
- 2008** **Participant with the Family Medicine Resident Recruitment Committee**
 University of Alberta
 Edmonton , AB
- 2005-2006** **Demonstrator in the Department of Family and Community Medicine**
 - Responsibilities: Lecturer, “Medical Ethics Course”
 - Supervisor for undergraduate medical trainees’ presentations and research activities
 King Saud University
 Riyadh, Saudi Arabia
- 2001** **Organizer with the Committee for Acceptance and Enrolment at King Saud University Unified Health Colleges Recruitment Program**
 King Saud University
 Riyadh, Saudi Arabia

Publications

Aaron S, Al-Watban L, Manca D. Scrotal Involvement in an Adult with Henoch-Schönlein Purpura.

Clin Rheumatol. 2013 Mar;32 Suppl 1:S93-5. doi: 10.1007/s10067-010-1555-7. Epub 2010 Sep 9

Sultan Al-Khenaizan, Lemmese Al-Watban. Parry-Romberg Overlap with Linear Morphea a Case Report.

Saudi Medical Journal 2005;vol.26(2):317-319